PATENT
Customer No.: 32425

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Bodo KUKLINSKI *et al.*

Serial No.: 10/511,882

Filed: October 19, 2004

For: USE OF A MARE'S MILK CONCENTRATE DRIED ON A HIGHLY-DISPERSED, BIOLOGICALLY INERT MATRIX

Confirmation No.: 6370

Group Art Unit: 1657

Examiner: SCHUBERG, Laura J.

Atty. Dkt. No.: SONN:057US

CERTIFICATE OF ELECTRONIC TRANSMISSION
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April 16, 2010 _____
Date Travis M. Wohlers

APPEAL BRIEF

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant submits this Appeal Brief to the Board of Patent Appeals and Interferences in response to the Office Action dated September 23, 2009. Appellant filed a Notice of Appeal on February 23, 2010. The two-month deadline for filing the Appeal Brief is April 23, 2010. The filing fee for the Appeal Brief is included. Should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed material, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Deposit Account No.: 50-1212/SONN:057US/10411925.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Nutropia Ernährungsmedizinische Forschungs GmbH.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF THE CLAIMS

Claims 9-10 and 14-22 are pending in this case and are rejected. Claims 1-8, 11-13, and 23-40 have been canceled. The rejection of claims 9-10 and 14-22 is being appealed.

IV. STATUS OF AMENDMENTS

No amendments are pending.

V. SUMMARY OF CLAIMED SUBJECT MATTER[1]

Independent claim 9 is directed to a method of treating neurodermatitis or psoriasis in a subject (Specification, p. 9, ln. 9-16; p. 19, ln. 5-23) comprising: obtaining a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix (Specification, p. 9, ln. 9-16; p. 19, ln. 5-23); and orally administering the composition to a subject (Specification, p. 20, ln. 2-14), wherein neurodermatitis or psoriasis is treated in the subject. (Specification, p. 25, ln. 1 to p. 35, ln. 12).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 9-10 and 14-22 are rejected under 35 U.S.C. § 103(a) as obvious over Fuchs *et al.* (WO 01/97634 A1, as translated by the USPTO (Evidence Appendix, Exhibit 1)) in view of SU

[1] Parentheticals citing to support in the specification for the claim language are exemplary and not meant to indicate that the specific citations are the only support in the specification for the claim language.

1740002 (as explained in the Russian Search Report (Evidence Appendix, Exhibit 2)) or Bühlbäcker (based on the description of this reference on page 8 of Appellant's patent application).

VII. ARGUMENT

A. The Claims Are Patentable Over Fuchs, SU 1740002, and Bühlbäcker

Claims 9-10 and 14-22 are patentable over the combination of Fuchs, SU 1740002, and Bühlbäcker at least because:

- Bühlbäcker reported that native mare's milk was ***ineffective*** in treating neurodermatitis if given alone.
- Fuchs provided no specific disclosure or suggestion that a milk concentrate dried on a biologically inert, disperse matrix can be used in a method treating neurodermatitis or psoriasis.
- SU 1740002 reported some beneficial effects in the treatment of neurodermatitis and eczema using a ***fermented*** mare's milk product.
- In view of the teachings of Fuchs, SU 1740002, and Bühlbäcker, a person of ordinary skill in the art would conclude that mare's milk needed to be ***fermented*** to have beneficial effects in the treatment of neurodermatitis.
- Furthermore, a person of ordinary skill in the art would not have dried the fermented mare's milk described by SU 1740002 using the drying process described by Fuchs, because the drying process would result in the loss of the alcohol and its attributed benefits of more sound sleep, reduction in skin itching, and relief of high nerve excitability.

1. The Legal Standard for Obviousness

In making a determination as to whether a *prima facie* case of obviousness exists, the examiner should: (A) determine the scope and content of the prior art; (B) ascertain the differences between the prior art and the claims at issue; (C) determine the level of ordinary skill in the pertinent art; and (D) evaluate evidence of secondary considerations. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). Secondary considerations may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results.

2. The Cited References Do Not Teach the Use of Mare's Milk Concentrate Dried on a Biologically Inert, Disperse Matrix for the Treatment of Neurodermatitis or Psoriasis

Fuchs discloses that highly unsaturated fatty acids, which occur mainly in plant oils and fish oil, are important for skin metabolism (Fuchs translation, p. 3). Fuchs further discloses that these unsaturated fatty acids may be dried on a biologically inert matrix (Fuchs translation, p. 7). While Fuchs also discloses that milk ***may*** be added to the matrix and fatty acid mixture before drying (Fuchs translation, p. 15), there is no specific disclosure or suggestion of using a milk concentrate dried on a biologically inert, disperse matrix in a method treating neurodermatitis or psoriasis.

SU 1740002 describes the use of koumiss, which is a fermented milk product, as a dietary supplement in the treatment of neurodermatitis and eczema. The fermentation process used to make koumiss results in a number of differences as compared to unfermented milk. Notably, koumiss contains alcohol and active microbial cultures not found in milk. As described in SU 1740002, the sedative effect of koumiss, which is likely due to the alcohol content, results in more sound sleep, reduction in skin itching, and relief of high nerve excitability (Translation of SU 1740002 at page 4 (Evidence Appendix, Exhibit 3)). In addition, SU 1740002 discloses

that koumiss has antibacterial properties (Translation of SU 1740002 at page 4 (Evidence Appendix, Exhibit 3)), which are likely attributable to the active cultures involved in the fermentation process. Thus, many of the beneficial properties of koumiss are attributable to components that are not present in native mares milk or a milk concentrate dried on a biologically inert, disperse matrix.

Bühlbäcker described the dietetic treatment of neurodermatitis with a native mare's milk (Specification, p. 8). Bühlbäcker reported that mare's milk was ***ineffective*** in treating neurodermatitis if given alone (Specification, p. 8). Even when combined with additional therapeutic measures, dietetic treatment with mare's milk required a minimum treatment time of 10 months (Specification, p. 8).

Thus, none of the references teach the use of mare's milk concentrate dried on a biologically inert, disperse matrix for the treatment of neurodermatitis or psoriasis. And, as explained in the following section, a person of ordinary skill in the art would not have had a reason to modify or combine these references to achieve the method recited in the current claims.

3. Upon Reading the Cited References, A Person of Ordinary Skill in the Art Would Have Been Led in a Direction Divergent from the Path Taken by the Appellant

As discussed above, Bühlbäcker reported that mare's milk was ***ineffective*** in treating neurodermatitis if given alone. SU 1740002, on the other hand, reported some beneficial effects in the treatment of neurodermatitis and eczema using the ***fermented*** milk product koumiss. Fuchs provided ***no*** specific disclosure or suggestion that a milk concentrate dried on a biologically inert, disperse matrix can be used in a method treating neurodermatitis or psoriasis. Thus, in light of the teachings of Fuchs and Bühlbäcker, a person of ordinary skill in the art would have no reason to expect that the a mare's milk concentrate dried on a biologically inert, disperse matrix would be any more effective at treating neurodermatitis or psoriasis than the

native mare's milk disclosed in Bühlbäcker. Further in light of the teachings in SU 1740002, a person of ordinary skill in the art would have been led to ferment the mare's milk in order to increase its effectiveness.

Thus, to improve efficacy of mare's milk in treating neurodermatitis and psoriasis, the teachings of Bühlbäcker and SU 1740002 would suggest to a person of ordinary skill in the art that one would need to ferment the mare's milk. There is no teaching or suggestion that drying the fermented mare's milk would have a beneficial effect. In fact, the drying process would be incompatible with the teachings of SU 1740002 regarding the sedative effect of the alcohol in the koumiss (SU 1740002 at page 4); because drying would result in the loss of the alcohol through evaporation. Accordingly, drying koumiss would deprive it of the benefits of more sound sleep, reduction in skin itching, and relief of high nerve excitability attributed to the alcohol by SU 1740002 (SU 1740002 at page 4). If a proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01(V). If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. MPEP § 2143.01(VI).

4. The Claimed Method Provides Surprisingly Successful Results in Treating Neurodermatitis and Psoriasis.

a) The Working Examples in the Specification

In the working examples provided in the present specification, marked improvement in symptoms were reported in the three neurodermatitis patients given the dried mare's milk preparation (Examples 1-3, p. 24-28). This improvement was evident at the first follow-up visit at ***one month*** and was sustained over the course of the study. The only other measures taken by

the patients were greasing ointments and oil baths. Additionally, Examples 4-6 (pages 30-34) in the specification demonstrated a clear and sustained improvement in three reported psoriasis patients given the dried mare's milk preparation. The improvement was evident in all three patients at the first follow-up visit at ***six weeks***.

b) The Fuchs Declaration

As further evidence of the surprisingly successful results achieved by treating neurodermatitis and psoriasis according to the claimed method, Appellant provided a declaration under 37 C.F.R. § 1.132 from Norbert Fuchs ("Fuchs Declaration") (Evidence Appendix, Exhibit 4) describing additional studies showing that orally administering a mare's milk concentrate dried on a biologically inert, disperse matrix was therapeutically effective in treating human patients with neurodermatitis or psoriasis. The dried mare's milk concentrate used in the studies described in the Fuchs Declaration was formulated as described on page 19, line 7 to page 20, line 1 of the patent application (Fuchs Declaration, para. 4). Following a baseline examination, the dried mare's milk concentrate was administered to the patients once per day (Fuchs Declaration, para. 4). Follow-up examinations were performed approximately one month, two months, and three months after the baseline examination (Fuchs Declaration, para. 4).

In the neurodermatitis (ND) study, nine patients with moderate to severe ND were treated with the dried mare's milk composition (Fuchs Declaration, para. 5). As described in paragraphs 6 and 7 of the Fuchs Declaration, significant improvement was observed in all patients over the course of the study, with the improvement in some of the patients being evident after only about one month of treatment.

In the psoriasis study, twelve patients with psoriasis were treated with the dried mare's milk composition (Fuchs Declaration, para. 9). The mean PASI decreased from a baseline of 11.4 to 6.8 at the first follow-up examination, 4.3 at the second follow-up examination, and 3.8 at

the third follow-up examination (Fuchs Declaration, para. 9). Several of the patients showed significant improvement as early as the first follow-up examination. Improvement was most dramatic in patients with the highest baseline PASI scores (Fuchs Declaration, para. 9).

c) Summary

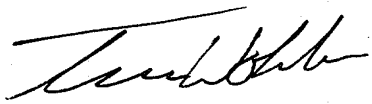
The evidence in the specification and the Fuchs Declaration demonstrate that the claimed method is not only therapeutically effective, but that it is therapeutically effective in a short period of time. In contrast, Bühlbäcker found that the dietetic treatment with a native mare's milk required a minimum treatment time of ***10 months***. In addition, Bühlbäcker reported that mare's milk was ***ineffective*** in treating neurodermatitis if given alone. Thus, a person of ordinary skill in the art would not have expected the dried mare's milk composition described in the present specification to be effective at treating neurodermatitis and psoriasis in less than three months, and in many cases in only one month.

SU 1740002 describes the use of koumiss as a dietary supplement in the treatment of neurodermatitis and eczema. The fermentation process used to make koumiss results in a number of changes to the milk. As noted in SU 1740002, the sedative effect of koumiss, which is likely due to the alcohol content, results in more sound sleep, reduction in skin itching, and relief of high nerve excitability (SU 1740002 at page 4). In addition, SU 1740002 discloses that koumiss has antibacterial properties (SU 1740002 at page 4), which are likely attributable to the active cultures involved in the fermentation process. Thus, a person of ordinary skill in the art would have been surprised that the dried mare's milk composition described in the present specification was effective at treating neurodermatitis and psoriasis given that it did not contain the alcohol or active cultures to which many of the beneficial effects of koumiss were attributed.

5. Conclusion

In view of the above, Claims 9-10 and 14-22 are patentable over the cited references. Appellants, therefore, request that the Board reverse this rejection.

Respectfully submitted,



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Date: April 16, 2010

VIII. APPENDIX A – APPEAL CLAIMS

9. A method of treating neurodermatitis or psoriasis in a subject comprising:
obtaining a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix; and
orally administering the composition to a subject, wherein neurodermatitis or psoriasis is treated in the subject.

10. The method of claim 9, wherein the subject is a human.

14. The method of claim 9, wherein the matrix is a highly disperse silicon dioxide.

15. The method of claim 9, wherein the mare milk concentrate was dried at a temperature of from 10 to 50°C.

16. The method of claim 15, wherein the mare milk concentrate was dried at a temperature of from 35 to 40°C.

17. The method of claim 9, wherein the mare milk concentrate was dried at a pressure of from 1 to 50 mbar.

18. The method of claim 17, wherein the mare milk concentrate was dried at a pressure of from 10 to 30 mbar.

19. The method of claim 9, further comprising drying the mare milk concentrate on the matrix.

20. The method of claim 9, wherein the composition further comprises at least one essential fatty acid.

21. The method of claim 20, wherein the essential fatty acid is a vegetable essential fatty acid.

22. The method of claim 9, wherein the composition further comprises at least one of hydrogen carbonate, potassium, carbonate, citrate, calcium, magnesium, vitamin C, vitamin E, niacin, zinc, iron, beta-carotene, pantothenic acid, manganese, vitamin B6, vitamin B2, vitamin B1, copper, sodium, biotin, folic acid, molybdenum, selenium, xanthan, fructose, citric acid, or vitamin B12.

IX. APPENDIX B - EVIDENCE APPENDIX

Exhibit 1 – USPTO Translation of Fuchs *et al.* (WO 01/97634 A1); first cited in the Office Action mailed May 11, 2006.

Exhibit 2 – Russian Office Action citing SU 1740002; filed in the Information Disclosure Statement dated April 23, 2007.

Exhibit 3 – English Translation of SU 1740002; filed in the Information Disclosure Statement dated October 24, 2007.

Exhibit 4 – Fuchs Declaration; filed July 17, 2008.

X. APPENDIX C - RELATED PROCEEDINGS

None

EXHIBIT 1

PTO 06-2490

International Patent
Document No. WO 01-97634 A1

METHOD FOR PRODUCING A DRY CONCENTRATE OF AN UNSATURATED FATTY ACID

[Verfahren zur Herstellung von ungesaettigtem Fettsaeure-Trockenkonzentrat]

Norbert Fuchs et al

UNITED STATES PATENT AND TRADEMARK OFFICE
Washington, D.C. February 2006

Translated by: Schreiber Translations, Inc.

Country	:	International, based on an Austrian patent application
Document No.	:	WO 01/97634 A1
Document Type	:	Publication of international application with international search report
Language	:	German
Inventor	:	Norbert Fuchs and Peter Koessler
Applicant	:	Oekopharm Forschungs- und Entwicklungs-GmbH, Unterberg, Austria
IPC	:	A 23 L 1/22
Application Date	:	June 19, 2001
Publication Date	:	December 27, 2001
Foreign Language Title	:	Verfahren zur Herstellung von ungesaettigtem Fettsaeure-Trockenkonzentrat
English Title	:	**METHOD FOR PRODUCING A DRY CONCENTRATE OF AN UNSATURATED FATTY ACID**

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METHOD FOR PRODUCING A DRY CONCENTRATE OF AN UNSATURATED FATTY ACID

The invention concerns a method for producing an unsaturated fatty acid dry concentrate as well as a compound comprising at least one unsaturated fatty acid, and foods, beverages and medications that comprise the compound.

Fatty acids (alkenoic acids) are components of lipids, phosphoglycerides, glycolipids, cholesterol esterases and waxes. They consist of a long, generally unbranched hydrocarbon chain and a terminal carboxyl group. The chain is either saturated or contains one or several non-conjugated cis double bonds; the latter are characterized as fatty acids. The cytochrome-b_5-ADPH-dependent oxygenase system is missing in superior animals, for which reason linoleic and linolenic acid belong to the essential fatty acids for these, that is, their need must be covered with the food intake.

Up until a few years ago, linoleic acid (omega 6 fatty acid; C 18:2 (9,12)) in dietetic foods was considered as the general value-determining factor for supplying unsaturated fatty acids; according to new scientific discoveries, the biological and

[1] Numbers in the margin indicate pagination in the foreign text.

essential importance of further unsaturated fatty acids has become the center point of attention, for example, linolenic acid, stearidonic acid, oleic acid, erucic acid, nervonic acid, palmitoleic acid, and vaccenic acid. These (highly) unsaturated fatty acids are very important in biological and clinical nutrition medicine, especially for the prostaglandin (also inflammatory) metabolism, the heart and vascular system, the carbohydrate metabolism (diabetes), obesity, for the skin metabolism (neurodermatitis, psoriasis), the hormonal metabolism, for the performance of the central nervous system, the lungs (asthma), the joints (arthritis), the immune system (allergies, cancer, AIDS), autoimmune disorders, degenerative diseases of the joints, growth processes of children and adolescents, metabolism of athletes and heavy workers, and ageing processes. For an optimal health is accordingly necessary a sufficient and balanced supply of (highly)

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unsaturated fatty acids.

Unsaturated fatty acids occur in different concentrations mainly in natural plant oils, in which they have a consistent oily characteristic. A few of these oils, in particular hemp oil, linseed oil and fish oil, have in addition a strong penetrating

intrinsic odor and flavor, which considerably limits a broad use of these oils, despite their high health promoting value.

A further problem in connection with foods enriched with unsaturated fatty acids is that the natural oils, which are consequently rich in unsaturated fatty acids, have a very limited shelf life and their oily consistency considerably limits their usefulness. In order to circumvent these mentioned disadvantages and produce products enriched with unsaturated fatty acids, which also find broad acceptance among the consumers, these oils are processed by means of technically complicated processes. Because of the strict production conditions required for this processing, however, the unsaturated fatty acids are modified to such an extent that they lose their high health promoting value. The processing of the mentioned oils into medicines, such as capsules, tablets, or liquids, in turn also satisfies only partially the daily requirement doses of physiological nutrition, which are within the gram range, precisely because of the dose volumina, which is limited by the described medicament forms.

In WO 87/03899 is described a process for the production of an omega 3 concentrate, in which the fatty acid fraction of fish oil is esterified at ambient temperature. In addition, after a heating to between 50 and 90°C and a subsequent cooling to 0°C,

the alkyl ester is precipitated and separated. An additional purification by extraction with a solvent produces the desired product. This process has several steps, however, in which the unsaturated fatty acids are subjected to relatively demanding conditions (great temperature fluctuations, different solvents and buffers, et cetera), so that part of the unsaturated fatty acids are modified or lost.

United States patent 6,030,645 concerns dry particles,

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comprising a oleophilic active substance, which is dispersed in a carrier material, in which the particles are coated with a compound containing calcium silicate. The oleophilic substance is, for example, arachidonic acid, carotenoids, et cetera. As carrier material is disclosed, inter alia, cellulose, maltodextrin, alginate, lactate, rubber, gelatin, sugar, sugar alcohol and starch. These particles are produced by mixing the oleophilic substance with the carrier material, and spraying this mixture into the calcium silicate, so that the oleophilic particles that are produced by the spraying are coated with calcium silicate. The particles are subsequently dried.

According to JP 6181725 A, a compound, comprising an easily oxidizable oily substance is introduced into a porous carrier by

means of a reduction of the pressure in such a way that the compound displaces the air in this porous carrier.

FR 2 758 055 A1 concerns a powdery substance, comprising oil based on unsaturated fatty acids, and an absorbent agent, possibly starch. The oil and the absorbing agent are homogenized and sprayed in order to obtain microparticles, whereupon the water contained in these microparticles is evaporated.

In United States patent 5,106,639 A is described a process for producing food supplements in which a carrier, an emulsifier, and an oil, comprising omega 3 fatty acids, are mixed and then dried to a powder. The carrier can be, for example, soybean protein, starch, pectin, gelatin, collagen, casein, and the like.

EP 0 424 578 A1 concerns a dry mixture, comprising an oil with unsaturated fatty acids and caseinate, in which these two substances are mutually mixed, whereupon the compound is dried.

In DE 4 411 414 C1 is described a product for enteral delivery with fatty acids and/or amino acids, as well as a process for producing this product, in which the fatty acids are embedded in the amylase helix by means of a joint extrusion with starch, so that inclusion complexes are formed. The compound is then dried.

United States patent 4,559,222 A concerns a compound, comprising a medicament, in which this compound comprises also mineral oil and silicon dioxide.

The above-described processes have, however, the disadvantage that high-quality oils with high proportions of unsaturated fatty acids cannot be treated with sufficient care, so that an excessively high quantity of unsaturated fatty acids is lost during the course of the process.

It is an object of the invention to make available a process for producing a concentrate from unsaturated fatty acids, in which the above-mentioned disadvantages are circumvented, and in which however the high health promoting value of the unsaturated fatty acids can be maintained. By means of such a concentrate should be made available doses with a sufficient quantity of unsaturated fatty acids, which do not have an excessively large volume. The process should ensure a fine surface distribution of oil particles and an exact dosage of the quantity ratios of fatty acids and carrier matrix.

The process according to the invention of the kind described above is characterized in that a substance comprising at least one unsaturated fatty acid is applied on a biologically inert matrix with a large surface and then dried. Under "substance"

is understood within the scope of the invention, an oil, preferably an untreated oil, as well as also any other compound comprising at least one unsaturated fatty acid. Through the application of the substance on a biologically inert matrix with large surface is attained that the substance is distributed over as small a volume as possible. In this way, it is possible to dry the substance rapidly and under mild conditions and to make it available in high concentrations in a form that remains stable during storage. It is important therein that the matrix is biologically inert and that the unsaturated fatty acid(s) are thus not attacked or modified by it. The unsaturated fatty acids adhere to the matrix, whereby they (1) are easy to handle and (2) the matrix offers a specific protection against other

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substances that may attack the unsaturated fatty acids. For a good distribution and sufficient drying of the unsaturated fatty acids, it is important that the biologically inert matrix has a large surface, that is, a surface of 50-1000 m^2/g.
Under matrix with a "large surface" is understood within the scope of the invention a carrier that is highly dispersible. Through the application, possibly by spraying, of the fatty acids on the highly disperse matrix, fine fatty acid droplets accumulate on the finely distributed matrix particles. In this

way is ensured an optimal fine surface distribution of the fatty acid particles as well as an exact dosage of the quantity ratios of fatty acids to carrier matrix. In this way, it is possible for the first time to concentrate and dry the temperature and oxygen sensitive fatty acids in a mild manner and without losses or without significant losses. In contrast to the porous carrier materials of the state of the art, the highly dispersible matrix allows a dry, highly concentrated fatty acid product to be obtained. In this way, high-quality oils, possibly high-quality plant oils with large proportions of thermally unstable and oxygen sensitive fatty acids, are joined with the matrix and dried at a mild temperature.

The matrix has preferably an average surface of at least 100 m^2/g, especially preferably at least 150 m^2/g, and even more especially preferably at least 200 m^2/g, and most preferably at least 400 m^2/g.

The average particles size of the matrix amounts, for example, to a maximum of about 900 nm, preferably a maximum of 500 nm, particularly preferably a maximum of 250 nm, a maximum of 100 nm, a maximum of 50 nm, a maximum of 25 nm, and most preferably a maximum of 15 nm.

The combination of the unsaturated fatty acids on the biologically inert matrix and the additional drying ensures that

a dry concentrate with unsaturated fatty acids without oily consistency and penetrating intrinsic odor and flavor is made available. A considerably improved shelf life is also provided. In addition, the production process can also be carried out

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rapidly and economically. Finally, the compounds according to the invention can be easily and simply further processed by the food industry.

A further advantage consists in that practically no loss of unsaturated fatty acids occurs as with the conventional processes, for example, extraction processes.

It is particularly advantageous if the substance is applied by means of nozzles on the matrix. In this way, it is ensured that the substance is finely distributed over the matrix already before applying the substance on the matrix and in this way a uniform fine distribution of the matrix is ensured.

For a thorough mixing, it is advantageous if the matrix and fatty acid mixture is mixed in a mixing system, in particular by means of a mixing screw conveyor. Any of the mixing systems (with mixing screw conveyor) known from the state of the art, in which the mixing container can be fully sealed, can be used. It is advantageous if in addition vibrators are also mounted on the container wall, which improves the mixing of difficult to mix

raw materials. The mixing accuracy can be further improved by means of a tilting and swaying motion of the mixing container. The mixture is refined by means of shaving heads and tubers and agglomerations that could form in the mixing mass are reduced to small pieces. It is advantageous if parameters, such as the mixing time, injection time, injection pressure, tilting angle, vibrators, and shaving head connection can be programmable or adjustable. In this way, it is easily possible for the person skilled in the art within the food industry sector to optimize the process for all substances and surfaces. An example of a suitable mixing system is the batch mixer "Prodima AC-LI/500." For a uniform mild and still fast drying, it is advantageous if the matrix and fatty acid mixture is dried in a vacuum. This vacuum drying is generally known to the persons skilled in the art. During vacuum drying, the mixture can be constantly mixed, for example, in a boiler, by means of an agitator. The vapor produced by means of the vacuum drying can be condensed and

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discharged into a water container. The boiler is preferably rotatable and reclined and can have any size, for example, 500 to 1000 liters. The system is preferably temperature or pressure controlled.

A particularly advantageous drying is characterized in that the matrix is dried at 1-50 mbar, especially at 10-30 mbar. In this vacuum is ensured a gentle drying without temperature damage. It is particularly advantageous if the matrix and fatty acid mixture is dried at 10 to 50°C, in particular at 30 to 36°C. In this working area occurs no damage of the unsaturated fatty acids. The boiler is heated, for example, by means of a control to a constant temperature. For this purpose, the drum can be provided with a double shell for hot water, which is heated via the heat recovered from the cooling device. A continuous flow water heater can also be incorporated in order to produce additional heat.

The substance is preferably applied on a silicon matrix, for example, a SiO_2 matrix. This matrix is biologically absolutely inert and has furthermore a sufficiently large surface, in order to make available a matrix that is advantageous for the process. It is especially advantageous if the substance is applied on a highly dispersed silicon dioxide matrix. This matrix is particularly well suited for the application of unsaturated fatty acids and subsequent drying.

The matrix is produced, for example, from Aerosil®, a highly disperse silicic acid with more than 99.8% SiO_2 content. This matrix is composed of amorphous sphere-shaped particles, which

have a diameter of about 10 to 20 nm. With a volume of approx. 15 ml, 1 g of Aerosil® has a surface of 100 to 400 m^2. This matrix is particularly well suited for the process according to the invention.

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A particularly advantageous process is characterized in that linseed oil, safflower oil, borage oil, hemp oil, soybean oil, pumpkinseed oil, sunflower oil, sesame oil, evening primrose oil and/or fish oil are applied as substance on the matrix. These oils comprise different concentrations of (highly) unsaturated fatty acids (see Tables 1 to 3). If these plant oils are applied in natural state on the matrix, they have an extremely high health promoting value with reference to their content of unsaturated fatty acids. The process is also carried out rapidly and economically.

A substance comprising (highly) unsaturated fatty acids, in particular omega 3, omega 6, omega 7, and/or omega 9 fatty acids is preferably applied on the matrix. Either single purified fatty acids can be used or also a mixture of two or more of these fatty acids. Plant oil comprising these fatty acids can also be used.

A particularly advantageous process is characterized in that 1 to 3, in particular 1.5, weight parts of substance for each

weight part of matrix are applied on the matrix. In this way is attained an ideal ratio of unsaturated fatty acids with respect to the matrix, so that a maximum quantity of fatty acids is applied on the necessary amount of matrix that is necessary for it, and the largest possible surface is obtained for the smallest possible volume of fatty acid dry concentrate.

In order to obtain the most durable product possible, it is advantageous if at least one stabilizer, in particular an antioxidant, is added to the matrix and fatty acid mixture. D,L-alpha tocopherol and ascorbyl palmitate are particularly suitable as highly unsaturated fatty acids. In this way, the shelf life of the dry concentrate is increased and the stability, in particular with regard to further processing, is improved.

It is also particularly preferred if at least one aromatic and/or flavor correcting substance is added to the matrix and fatty acid mixture. In this way, any possibly remaining unpleasant odor or flavor of the unsaturated fatty acids is

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stopped. Under odor or flavor correcting substance is understood within the scope of the invention not only a concealment of the odor or flavor, but also the addition of a

pleasant odor or flavor, for example, a sweetener, a fruity flavor, etheric oils, et cetera.

It is particularly advantageous if ethereal lemon oil is used as odor or flavor correcting substance. This substance is particularly well suited as additive for unsaturated fatty acids.

A further advantageous process is characterized in that milk, in particular pasteurized milk, is added to the matrix and fatty acid mixture before drying. Any type of milk can be added, in particular cow's, mare's, donkey's, colostral, goat's and/or sheep's milk. Dry concentrates of the mentioned milk species or fractions of these have, inter alia, immunostimulating effects on the human and animal organism. The content of these essential nutrients in milk concentrates according to need is increased by adding (highly) unsaturated fatty acids and the biological value of milk concentrates is improved in this way. 1 to 2, preferably approximately 1.5, weight parts of milk are added for each weight part of matrix and fatty acid mixture. This quantity ratio has shown to be particularly advantageous, so that the advantages of the addition to the milk are attained without disturbing the further drying process or cause negative effects on the unsaturated fatty acids.

For the ingestion of these concentrates, it is particularly advantageous if the matrix and fatty acid mixture is processed after drying, in particular to powder, capsules, tablets, or liquids. Further additives can also be added, possibly vitamins, flavor additives, mineral substances, medicaments, et cetera. The necessary daily dose of fatty acids, for example, can also be processed to form a unit, such as tablets or capsules.

It is particularly preferred if the matrix and fatty acid mixture is added to foods and/or beverages after drying, in

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particular baby food, milk products and/or baking mixes. Since the fatty acid dry concentrate does not have an oily consistency and does not have an unpleasant odor or flavor, the food or beverage is not fundamentally changed by this addition, so that none or hardly any additional process steps are necessary.

A further aspect of the invention concerns a compound comprising at least one unsaturated fatty acid and a matrix with large surface. With regard to the unsaturated fatty acid and the matrix applies in turn what was mentioned above, so that the compound is preferably a concentrate of at least one unsaturated fatty acid. This compound can have any imaginable consistency, but should preferably be made available as dry concentrate. The

compound surprisingly does not have an oily consistency caused by the combination of the unsaturated fatty acid and the matrix with large surface as is the rule usually in the prevalent products comprising unsaturated fatty acids. This compound does also not have the otherwise occurring penetrating intrinsic odor and flavor, and is, in particular as dry concentrate, considerably longer lasting.

The matrix is preferably a silicon matrix, for example, a SiO_2 matrix, in particular a highly dispersed silicon dioxide matrix. This matrix is particularly well suited as inert basic substance for a compound comprising an essential fatty acid, has a large surface, and is very well suited for any further processing.

The compound comprises preferably linseed oil, safflower oil, borage oil, hemp oil, soybean oil, pumpkinseed oil, sunflower oil, sesame oil, evening primrose oil and/or fish oil. These oils have a high content of (highly) unsaturated fatty acids and in particular a high health promoting value in natural state.

It is particularly advantageous if the compound comprises at least one highly unsaturated fatty acid, in particular omega 3, omega 6, omega 7, and/or omega 9 fatty acids. These essential fatty acids are particularly important for numerous biochemical

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processes and also for the structure of substances that are of vital importance.

The compound comprises advantageously 0.1 to 3 weight parts of the at least one unsaturated fatty acid for each weight part of matrix. Naturally, in case natural oil is utilized for the production of the compound, the concentration and also the type of unsaturated fatty acid can vary more or less strongly. This ratio, which naturally also depends from the respective further processing, is however optional as a rule.

The compound preferably comprises at least one stabilizer, in particular an antioxidant, at least one odor and/or flavor correcting substance, in particular ethereal lemon oil, and/or dry milk, in particular pasteurized milk. These additives optimize the properties of the compound, simplify their further processing, and have a particularly advantageous effect on the final product, for example, with regard to the shelf life or flavor.

A particularly advantageous compound is characterized in that it comprises 1 to 2, in particular 1.5, weight parts of milk for each weight of matrix and fatty acid mixture. In this way is achieved an optimal consistency.

For a good shelf life and simple further processing, it is preferred that if compound is dried. Particularly preferred are compounds having an A_w value of 0.8.

A further aspect of the invention is to make available a food, a beverage, or a medicament that is characterized in that it is mixed with the compound according to the invention in the manner described above. The food or beverage can be any commercially available product, for example, a basic food or a luxury food item. The consistency of the food is not essential, it can be either fluid, such as, for example, a fruit juice, viscous, such as yoghurt, marmalade, oil, et cetera, or solid, such as a

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baking mix, cereal, or the like. The compound can, of course, also be made available in highly concentrated form as an effervescent tablet, syrup or the like. Also the medicament, which comprises the compound according to the invention, can have any kind of imaginable form and consistency, for example, the form of a tablet, liquid, powder or capsule.

The process according to the invention will now be explained based on the following example, which however does not represent a limitation.

Example:

In a mixer of the Prodima "Batch Mixer Prodima AC-LT/500," brand, in which a highly dispersed silicon dioxide is placed, the following components are injected under steady stirring via fine nozzles into the spraying system:

- Linseed oil: 2 weight parts (see Table 1)
- Safflower oil: 1 weight part (see Table 2)
- Borage oil: 1 weight part (see Table 3)
- D,L-alpha tocopherol and ascorbyl palmitate as stabilizers
- Odor and flavor correcting substances (ethereal lemon oil)

Table 1: Linseed Oil (g of fatty acids/100 g of fat)

Palmitic acid	5.95
Stearic acid	3.60
Oleic acid	18.20
Linoleic acid	13.90
Linolenic acid	54.20

Table 2: Safflower Oil - Fatty acid compound % (subject to fluctuations)

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C14:0	0.1 - 0.2
C14:1	0
C16:0	6.7 - 7.7

C16:1	0
C18:0	2.4 - 2.7
C18:1	12.6 - 13.6
C18:2	75.7 - 77.1
C18:3	0 - 0.2
C20:0	0.3 - 0.4
C20:1	0 - 0.2
C22:0	0 - 0.2
C22:1	0
C24:0	0

Table 3: Borage Oil

Acid value (mg KOH/g oil)	0.1 %
Gamma linolenic acid content	23.6%

The silicon dioxide placed in the mixing system has a ratio of 2.7 weight parts. The EFS powder obtained in this way (EFS = Essential Fatty Acids) has a total content of 48.3% of essential fatty acids with the following distribution pattern:

Table 4:

W-3 Fatty Acids:	
C 18:3 (9, 12, 15) alpha linolenic acid	10.5%
C 18:4 (4, 8, 12, 15) stearidonic acid	0.01%

W-6 Fatty Acids:	
C 18:2 (9, 12) linoleic acid	16.8%
C 18:3 (6, 9, 12) gamma linolenic acid	2.5%
W-9 Fatty Acids:	
C 18:1 (9) Oleic acid	7.8%
C 22:1 (13) Erucic acid	0.3%
C 24:1 (15) Nervonic acid	0.12%

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W-7 Fatty Acids:	
C 16:1 (9) Palmitoleic acid	0.02%
C 18:1 (11) Vaccenic acid	0.05%

In a "mare's milk system" evaporating apparatus were placed approximately 41 kg of EFS concentrate. Approximately 57 kg of pasteurized milk (optionally cow's, mare's, donkey's, colostral, goat's, or sheep's milk) are then added and evaporated for 24 hours at a temperature of 32°C under vacuum conditions (approx. 10 mbar). After 24 hours, the aqueous portion of the added milk is evaporated at a mild temperature. The residue obtained by

means of this process was a milk-EFS concentrate with a high proportion of (highly) unsaturated fatty acids in stable, organoleptically acceptable, and highly concentrated powder form. This powder form can be further processed to different products (baking mixes, baby food, milk products) and also in different medicament forms, such as capsules, tablets, et cetera.

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Patent Claims:

1. A process for producing an unsaturated fatty acid dry concentrate, wherein a substance comprising at least one unsaturated fatty acid is applied on a biologically inert matrix with a large surface and then dried.

2. The process of claim 1, wherein the substance is applied by means of nozzles on the matrix.

3. The process of claim 1 or 2, wherein the matrix and fatty acid mixture is mixed in a mixing system, in particular by means of a mixing screw conveyor.

4. The process of claim 3, wherein the matrix and fatty acid mixture is vacuum dried.

5. The process of claim 4, wherein the matrix and fatty acid mixture is dried at 1-50 mbar, especially at 10-30 mbar.

6. The process of claim 4 or 5, wherein the matrix and fatty acid mixture is dried at 10 to 50°C, especially at 30 to 36°C.

7. The process of claims 1 to 6, wherein the substance is applied on a silicon matrix.

8. The process of claim 7, wherein the substance is applied on a highly dispersed silicon dioxide matrix.

9. The process of one of the claims 1 to 8, wherein linseed oil, safflower oil, borage oil, hemp oil, soybean oil, pumpkinseed oil, sunflower oil, sesame oil, evening primrose oil and/or fish oil are applied as substance on the matrix.

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10. The process of one of the claims 1 to 9, wherein a substance comprising highly unsaturated fatty acids, in particular omega 3, omega 6, omega 7, and/or omega 9 fatty acids, is applied on the matrix.

11. The process of claims 1 to 10, wherein 1 to 3, in particular 1.5, weight parts of substance are applied on the matrix for each weight part of matrix.

12. The process of one of the claims 1 to 11, wherein at least one stabilizer, in particular an antioxidant, is also added to the matrix and fatty acid mixture.

13. The process of one of the claims 1 to 12, wherein at least one odor and/or flavor correcting substance is added to the matrix and fatty acid mixture.

14. The process of claim 13, wherein ethereal lemon oil is added as odor and flavor correcting substance to the matrix and fatty acid mixture.

15. The process of one of the claims 1 to 14, wherein milk, in particular pasteurized milk, is added to the matrix and fatty acid mixture before drying.

16. The process of claim 15, wherein 1 to 3, especially approximately 1.5, weight parts of milk are added for each weight part of matrix and fatty acid mixture.

17. The process of one of the claims 1 to 16, wherein the matrix and fatty acid mixture is further processed after drying, in particular to a powder, capsules, tablets or liquids.

18. The process of one of the claims 1 to 17, wherein the matrix and fatty acid mixture is added after drying to foods and/or beverages, in particular to baby food, milk products, and/or baking mixes.

19. A compound comprising at least one unsaturated fatty acid

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and a matrix with a large surface.

20. The compound of claim 19, wherein the matrix is a silicon matrix.

21. The compound of claim 20, wherein the matrix is a highly dispersed silicon dioxide matrix.

22. The compound of one of claims 19 to 21, comprising linseed oil, safflower oil, borage oil, hemp oil, soybean oil, pumpkinseed oil, sunflower oil, sesame oil, evening primrose oil and/or fish oil.

23. The compound of one of the claims 19 to 22, comprising at least one highly unsaturated fatty acid, in particular omega 3, omega 6, omega 7, and/or omega 9 fatty acids.

24. The compound of one of the claims 19 to 23, comprising 0.1 to 3 weight parts of at least one unsaturated fatty acid for each weight part of matrix.

25. The compound of one of the claims 19 to 24, comprising at least one stabilizer, in particular an antioxidant.

26. The compound of one of the claims 19 to 25, comprising at least one odor and/or flavor correcting substance.

27. The compound of claim 26, comprising ethereal lemon oil as odor and flavor correcting substance.

28. The compound of one of the claims 19 to 27, comprising dry milk, in particular pasteurized milk.

29. The compound of claim 28, comprising 1 to 2, preferably approximately 1.5, weight parts of milk for each weight part of matrix and fatty acid mixture.

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30. The compound of one of the claims 19 to 29, wherein said compound is dried.

31. A food, which is mixed with a compound of one of the claims 19 to 30.

32. A beverage, which is mixed with a compound of one of the claims 19 to 30.

33. A medicament, which is mixed with a compound of one of the claims 19 to 30.

EXHIBIT 2

(19) Republik Österreich Patentamt

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(12) # PATENTSCHRIFT

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(54) SCHALUNGSFORM, VERFAHREN ZU DEREN HERSTELLUNG SOWIE EINRICHTUNG ZUR DURCHFÜHRUNG DES VERFAHRENS

AT 393 861 B

Die Erfindung betrifft zunächst eine Schalungsform, bestehend aus Aluminium od. dgl. Leichtmetall bzw. einer Leichtmetall-Legierung, zur Herstellung von Formkörpern aus Beton od. dgl. abrasivem Material.

Solche massive Schalungsformen besitzen dank ihrer robusten Gestaltung eine gute Wärmeleitfähigkeit und sind sowohl zum Kokillen- wie auch zum Druckguß gut geeignet, wobei sie im Hinblick auf das verwendete Material bloß ein vergleichsweise niedriges Gewicht aufweisen.

Die Verschleißfestigkeit solcher aus Leichtmetall bestehender Schalungsformen ist jedoch verhältnismäßig gering; insbesondere verringern die ausgeschwemmten Quarzbestandteile des Betons mit ihren abrasiven Eigenschaften die Lebensdauer und beeinträchtigen infolge allzurascher Abnutzung nach verhältnismäßig kurzem Gebrauch die Maßgenauigkeit solcher Schalungsformen. Eine solche Maßgenauigkeit ist jedoch bei der Herstellung verschiedener aus Beton herzustellender Produkte, insbesondere bei Beton-Dachsteinen, von erheblicher Bedeutung. Die vorbekannten aus Leichtmetall bestehenden Schalungsformen mußten somit schon nach etwa zweitausend Umläufen, das entspricht einer Lebensdauer von etwa drei bis vier Jahren, gegen neue Schalungsformen ausgetauscht werden.

Aus widerstandsfähigerem Material, wie Stahl, bestehende Schalungsformen sind aber, wenn sie massiv ausgeführt wurden, zu schwer; wenn sie hingegen aus Stahlblech hergestellt werden und vergleichsweise filigran ausgebildet sind, neigen sie zu Verformungen, ihre Wärmeleitfähigkeit ist zu gering und sie erweisen sich infolgedessen für eine industrielle Fertigung von Bauelementen aus abrasiven Werkstoffen als ungeeignet.

Aufgabe vorliegender Erfindung ist es, diesen Mängeln abzuhelfen und eine aus Aluminium od. dgl. Leichtmetall bzw. einer Leichtmetall-Legierung bestehende, massive Schalungsform zu schaffen, deren Gewicht materialbedingt gering ist, die aber dennoch eine hohe Verschleißfestigkeit besitzt und auch noch nach einer hohen Anzahl von Umläufen die darin hergestellten Produkte maßgenau zu formen vermag.

Erfindungsgemäß ist die Arbeitsfläche der Schalungsform mit einer aus Stahl bzw. einer Stahllegierung bestehenden Beschichtung versehen.

Eine solche Beschichtung, die beispielsweise durch Aufsprühen auf die vorerst gerauhte Schalungsform aufgebracht werden kann, verleiht der Arbeitsfläche die erforderliche Abriebfestigkeit und Dauerhaftigkeit. Die Maßhaltigkeit der Schalungsform kann gewahrt werden, ohne daß man sie besonders massiv und gewichtig ausbilden braucht.

Vorzugsweise besteht die Beschichtung aus einer Chrom-Nickel-Stahl-Legierung, also aus einem Material hoher Härte, das sich mit dem Basismaterial der Schalungsform gut und dauerhaft vereinen läßt.

Es hat sich gezeigt, daß schon eine Beschichtung einer Dicke von nur 100 bis 300 Mikron genügt, um das Auftreten von Fehlerstellen auch nach längerem Gebrauch der Schalungsform auszuschließen.

Die Erfindung betrifft des weiteren ein Verfahren zur Herstellung einer Schalungsform, demzufolge die Arbeitsfläche der zunächst unbearbeiteten Schalungsform durch eine Sandbestrahlung aufgerauht und sodann mit dem in schmelzflüssigem Zustand befindlichen Beschichtungsmaterial besprüht wird. Durch diese Aufrauhung wird ein ausgezeichneter Verbund zwischen der Beschichtung und dem Basismaterial gewährleistet; das zähe und hochfeste Material der Beschichtung vermag den Formänderungen der Basis, z. B. temperaturbedingten Formänderungen, ohne Schwierigkeit zu folgen, ohne dadurch Schaden zu erleiden.

Schließlich erstreckt sich die Erfindung auch auf eine Einrichtung zur Durchführung dieses Verfahrens, und zwar besteht eine solche Einrichtung aus zumindest einem Förderer, der nacheinander eine mit einem Sandstrahlgebläse ausgerüstete Kammer und sodann zumindest eine mit zumindest einer Spritzdüse ausgestattete Spritzkammer durchläuft.

Es empfiehlt sich, in dieser Spritzkammer zumindest zwei in Förderrichtung hintereinander angeordnete, gegenläufig quer zur Förderrichtung des Förderers bewegbare Spritzdüsen vorzusehen, um eine rasche und gleichmäßige Beschichtung zu erzeugen.

Ein Ausführungsbeispiel einer solchen Einrichtung ist an Hand der einzigen Zeichnungsfigur in einer schematischen Draufsicht veranschaulicht.

Die noch unbearbeiteten Schalungsformen (1) werden in der Förderrichtung (2) auf einem Förderer, z. B. einem Seilförderer (3), zunächst einer Kammer (4) zugeführt, in der sie einer Bestrahlung mit durch Injektordüsen versprühtem Korund-Sand od. dgl. unterzogen werden; auf das Aluminium, aus dem diese Schalungsformen (1) bestehen, wirkt diese Bestrahlung reinigend und aufrauhend, dient also der Verbesserung der Haftung des nachfolgend aufzubringenden Überzuges.

Die auf diese Weise vorbehandelten, an ihrer Arbeitsfläche aufgerauhten Schalungsformen (1') werden anschließend einer Spritzkammer (5) zugeführt, in der zwei quer zur Förderrichtung (2) bewegbare Spritzdüsen (6 und 7) vorgesehen sind, die zueinander gegenläufig über die Arbeitsfläche der Schalungsformen (1') stetig hin und her geführt werden. Diese Spritzdüsen (6 und 7) werden von einem Lichtbogen-Spritzaggregat (8) gespeist, an das sie über Zufuhrleitungen (9) angeschlossen sind.

Dem Spritzaggregat (8) wird das zu verarbeitende Beschichtungsmaterial in Drahtform zugeführt, dadurch kann bei vergleichsweise niedrigen Temperaturen gearbeitet werden. Die Temperaturen bleiben unterhalb 80 °C und es verringert sich infolgedessen die Gefahr von unerwünschten Formänderungen der Basis. Die Differenz zwischen der Temperatur des Aluminiums und der des Stahles ist gering und es entstehen beim Abkühlen keine inneren Spannungen, z. B. Schrumpfspannungen.

Die fertig beschichteten Schalungsformen (1") verlassen die Spritzkammer (5) mit Hilfe des Seilförderers

(3), dessen Antrieb mit (10) bezeichnet ist. Nach dem Verlassen der Spritzkammer (5) sind die Schalungsformen (1") mit einer Schicht bedeckt, die einem Gewicht von etwa 200 g pro Schalungsform entspricht.

Der Spritzkammer (5) in Förderrichtung (2) nachgeordnet kann ein zusätzliches Sandstrahlgebläse (11) zum Glätten der Beschichtung vorgesehen sein. Bei dem vergleichsweise harten Stahl der Beschichtung wirkt diese Sandbestrahlung glättend, abgesehen davon, daß die Möglichkeit besteht, für diese Nachbehandlung ein anderes Sandmaterial zu wählen, das diesem Zweck entspricht.

PATENTANSPRÜCHE

1. Schalungsform, bestehend aus Aluminium od. dgl. Leichtmetall bzw. einer Leichtmetall-Legierung, zur Herstellung von Formkörpern aus Beton od. dgl. abrasivem Material, **dadurch gekennzeichnet,** daß die Arbeitsfläche der Schalungsform mit einer aus Stahl bzw. einer Stahllegierung bestehenden Beschichtung versehen ist.

2. Schalungsform nach Anspruch 1, **dadurch gekennzeichnet,** daß die Beschichtung aus einer Chrom-Nickel-Stahl-Legierung besteht.

3. Schalungsform nach Anspruch 1 oder 2, **dadurch gekennzeichnet,** daß die Beschichtung eine Dicke von 100 bis 300 Mikron aufweist.

4. Verfahren zur Herstellung einer Schalungsform nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet,** daß die Arbeitsfläche der zunächst unbearbeiteten Schalungsform durch Sandbestrahlung gereinigt und aufgerauht und sodann mit dem in schmelzflüssigem Zustand befindlichen Beschichtungsmaterial besprüht wird.

5. Einrichtung zur Durchführung des Verfahrens nach Anspruch 4, **gekennzeichnet durch** zumindest einen Förderer (1), der nacheinander eine mit einem Sandstrahlgebläse ausgerüstete Kammer (4) und sodann zumindest eine mit zumindest einer Spritzdüse (6, 7) ausgestattete Spritzkammer (5) durchläuft.

6. Einrichtung nach Anspruch 5, **dadurch gekennzeichnet,** daß zwei in Förderrichtung (2) hintereinander angeordnete, gegenläufig quer zur Förderrichtung bewegbare Spritzdüsen vorgesehen sind.

7. Einrichtung nach einem der Ansprüche 1 bis 6, **gekennzeichnet durch** ein der Spritzkammer (5) in Förderrichtung (2) nachgeordnetes zusätzliches Sandstrahlgebläse (11) zum Glätten der Beschichtung.

Hiezu 1 Blatt Zeichnung

ÖSTERREICHISCHES PATENTAMT

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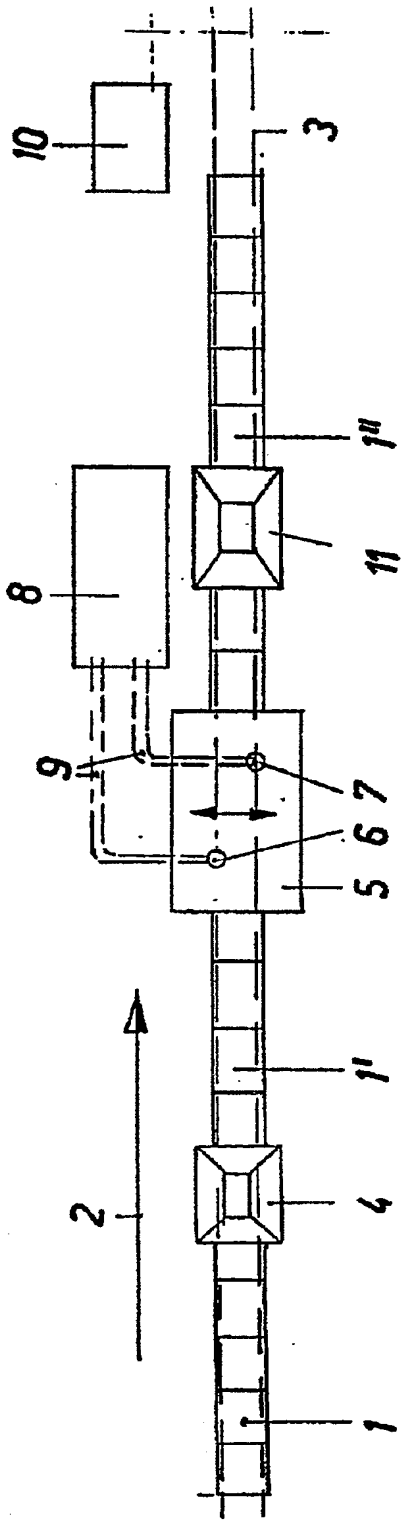
Blatt 1



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ФЕДЕРАЛЬНАЯ СЛУЖБА
ПО ИНТЕЛЛЕКТУАЛЬНОЙ
СОБСТВЕННОСТИ,
ПАТЕНТАМ И ТОВАРНЫМ ЗНАКАМ
(РОСПАТЕНТ)

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(54) СПОСОБ ПРОИЗВОДСТВА СУХОГО МОЛОЧНОГО ПРОДУКТА

Способ может использоваться в молочной промышленности. Антиоксидант агидол вносят в масляном растворе в количестве 0,005-0,01 мас.% в сырое молоко. Смесь гомогенизируют, сгущают и сушат. Антиоксидант агидол можно вносить в сухое молоко в сухом виде распылением порошка в количестве 0,05-0,1 мас.%. Способ позволяет уменьшить и подавить концерогенез, увеличить срок хранения готового продукта, т. к. жир кобыльего молока не прогоркает и сохранность витаминов составляет 70-80% через 1 год хранения в негерметичной таре. 5 з. п.ф-лы, 1 табл.

ОПИСАНИЕ ИЗОБРЕТЕНИЯ

Изобретение относится к производству диетических и лечебно-профилактических продуктов из кобыльего молока.

Наиболее близким техническим решением к данному является способ производства сухих молочных продуктов из коровьего молока, заключающийся в сгущении, гомогенизации, внесении антиокислителя, что связано с использованием спиртового раствора кварцетина ($C_{12}H_{10}O_{7}$ 2H_2O) [1]. Недостатком его является то, что используют спиртовый раствор, а присутствие спирта не всегда желательно.

Кобылье молоко сильно отличается от коровьего как по качественному, так и по количественному составу, (см. табл.).

Кобылье молоко по составу белка относится к альбуминовому. По содержанию жира кобылье молоко в среднем в 2 раза беднее коровьего, что связано с содержанием ненасыщенных жирных кислот, в основном незаменимых - пенолевой и линоленовой. Жир быстро прогоркает.

Концентрация лактозы в кобыльем молоке в 1,5 раза больше. Молочный сахар представляет собой дисахарид, состоящий из глюкозы и галактозы, и не идентичен коровьему.

Молоко кобыл в 5-10 раз богаче коровьего витамином С, каротина больше в 2-4 раза.

Кроме того, в процессе приготовления кумыса в нем синтезируются витамины группы В и витамин С.

Состав кобыльего молока и кумыса изучен недостаточно. Применение кумыса из кобыльего молока для лечения

различных заболеваний известно издревле (кроме онкологических), кумысолечение успешно применяется и в настоящее время в специализированных санаториях и лечебницах.

Экспериментально установлено, что сухой молочный продукт из кобыльего молока, получаемый по заявленному способу, и кумыс, приготовленный из него, обладают свойствами, уменьшающими и подавляющими канцерогенез.

Таким образом, добавление в кобылье молоко известного антиоксиданта 4-метил-2,6-дитретичный бутафенол (агидол), эмпирическая формула $C_{15}H_{24}O$, разрешенного Минздравом СССР для применения в пищевых продуктах, приводит к новому техническому результату.

В настоящее время технология сушки коровьего молока разработана досконально, производство оснащено совершенным и производительным оборудованием.

Проблема использования существующего оборудования для сушки кобыльего молока заключается а) в подборе режимов сушки из-за различий в составе молока коров и кобыл, б) в трудности сбора, хранения и транспортировки молока, т.к. кобыл обязательно необходимо доить 6-7 раз в сутки, кобылы отдают молоко небольшими порциями, накапливать его в течение суток нельзя, т. к. одно из самых неудобных свойств этого молока - оно не хранится и очень быстро загнивает, а жир в нем прогоркает.

Таким образом, достигаемый технический результат заключается в следующем: 1) заявляемый сухой молочный продукт и кумыс, приготовленный из него, обладает свойствами, уменьшающими и подавляющими канцерогенез; 2) несколько увеличивается время хранения сырого кобыльего молока, за которое можно накопить и транспортировать достаточное его количество, необходимое для полной загрузки сушильного оборудования; 3) в сухом молочном продукте жир кобыльего молока не прогоркает и сохранность витаминов составляет 70-80% через 1 год хранения в негерметичнои таре; 4) кобылье молоко обычно не выносит тепловой пастеризации, из-за денатурации специфического белка и быстрого окисления жира. Сырое кобылье молоко с добавлением антиоксиданта может подвергаться тепловой пастеризации, если в этом появится необходимость, т.к. обычно кобылье молоко не пастеризуют в связи с тем, что организм лошади резистентен к туберкулезу.

5) Полученный сухой молочный продукт обладает растворимостью 98,5-99% в теплой кипяченой воде, быстрорастворимость - также достигаемый технический результат.

Сущность способа заключается в следующем.

Вариант I, когда необходимо собирать молоко и хранить до получения достаточного объема. В очищенное и охлажденное кобылье молоко вводят растительное масло в количестве 0,5% с растворенным в нем агидолом в количестве 0,005-0,01%, смесь гомогенизируют и накапливают до необходимого объема. Затем смесь с температурой 45-60°С подают в вакуум-выпарной аппарат, температуру кипения в котором поддерживают 50-60°С и сгущают до плотности 1,13-1,15 г/см^3. Температура кипения смеси в вакуум-выпарном аппарате 60°С. Сгущенную смесь сушат распылением в поток горячего воздуха непосредственно после поступления ее из вакуум-выпарного аппарата. Температура воздуха на входе в башню 125-135°С, а на выходе из нее 60-65°С, в башне поддерживается разрежение воздуха 0,0033 МПа.

Вариант II, когда свежее молоко получают в достаточном объеме и накапливать его нет необходимости. Кобылье молоко с температурой 45-60°С подают в вакуум-выпарной аппарат, температуру кипения в котором поддерживают 50-60°С и сгущают до плотности 1,13-1,15 г/см^3. Температура кипения молока в вакуум-выпарном аппарате 60°С. Сгущенное молоко сушат распылением в поток горячего воздуха непосредственно после поступления его из вакуум-выпарного аппарата. Температура воздуха на входе в башню 125-135°С, а на выходе из нее 60-65°С.

Затем в сухое молоко во время операции рассева на встряхивающем сите вносят антиоксидант агидол в сухом виде распылением порошка в количестве 0,05-0,1%.

В зависимости от состава кобыльего молока, который колеблется по сезонам года, в готовом продукте содержится мас. %: лактоза 56-60; белок 13-19; жир 19-22, минеральные соли 3,5-4,0.

Пример 1. К 100 кг очищенного и охлажденного кобыльего молока добавляют 0,5 кг кукурузного масла с растворенным в нем 0,5 кг агидола, затем эту смесь гамогенизируют. Смесь с температурой 60°С подают в вакуум-выпарной аппарат, температура кипения в котором поддерживается 60°С, и сгущают до плотности 1,13 г/см^3. Температура кипения смеси в вакуум-выпарном аппарате не должна превышать 60°С, так как такая температура позволяет избежать денатурации специфических белков кобыльего молока. Сгущенную смесь сушат распылением в поток горячего воздуха непосредственно после поступления ее из вакуум-выпарного аппарата. Температура воздуха на входе в башню 125-135°С, а на выходе из нее 60-65°С, в башне поддерживается разрежение воздуха 0,0033 МПа.

Благодаря распылению площадь поверхности молока сильно возрастает, а мельчайшие частицы его, отдавая свою

злагу, до завершения сушки не успевают нагреться до температуры окружающей среды, поэтому процесс сушки при /казанном режиме не влияет на коллоидную структуру.

Получают 9,07 кг готового продукта следующего состава, мас %:

Белок - 15

Жир - 20

Лактоза - 59

Минеральные соли - 4,0

Влага - 3,0

Кислотность продукта - 8 Т

Сухой молочный продукт расфасовывают в тару или таблетируют.

Пример 2. 100 кг очищенного и охлажденного кобыльего молока сгущают и сушат как в примере 1, затем во время операции рассева на встряхивающем сите в сухое молоко вносят антиоксидант агидол в сухом виде распылением порошка в количестве 0,5 кг. В остальном все как в примере 1.

Источники информации

Авторское свидетельство СССР N 350451, опубл. 09.10.72 г.

ФОРМУЛА ИЗОБРЕТЕНИЯ

1. Способ производства сухого молочного продукта из кобыльего молока, включающий внесение антиоксиданта, гомогенизацию, сгущение смеси и сушку, отличающийся тем, что в качестве антиоксиданта вносят агидол ($C_{15}H_{24}O$).

2. Способ по п.1, отличающийся тем, что антиоксидант агидол вносят в сырое молоко в виде масляного раствора в количестве 0,005-0,01 мас.%.

3. Способ по п.1, отличающийся тем, что антиоксидант агидол вносят в сухое молоко путем распыления порошка в количестве 0,05-0,1 мас.%.

4. Способ по п.1, отличающийся тем, что сгущение проводят до плотности 1,13-1,15 г/см^3 в вакууме при температуре кипения 50 - 60°С.

5. Способ по п. 1, отличающийся тем, что сушку проводят до влажности 3,0-3,5% распылением в потоке воздуха с температурой на входе 125-130°С, на выходе 60-65°С, а разряжение воздуха составляет 0,0033 МПа.

6. Способ по п.1, отличающийся тем, что сухой продукт таблетируют.

ИЗВЕЩЕНИЯ К ПАТЕНТУ НА ИЗОБРЕТЕНИЕ

Код изменения правового статуса	**MM4A - Досрочное прекращение действия патентов РФ из-за неуплаты в установленный срок пошлин за поддержание патента в силе**
Дата публикации бюллетеня	**2002.11.27**
Номер бюллетеня	**33/2002**
Дата прекращения действия патента	**1999.06.08**

РИСУНКИ

Рисунок 1, Рисунок 2

Таблица

Показатели состава	Кобылье молоко	Коровье молоко
Белок	2%, преобладает альбумин, молоко *считается альбуминовым* В белке 50% казеина, 50% альбумина. Казеин кобыльего молока выпадает в осадок в форме чрезвычайно мелких хлопьев почти не ощутимых на язык и не меняющих консистенцию жидкости.	3% в котором преобладает казеин, который дает плотный сгусток нерастворимый в воде. В белке 85% казеина и 15% альбумина.
	В составе казеина окиси кальция 1,7%, фосфорного ангидрида 1,4 %	В составе казеина окиси кальция 4,43% фосфорн. ангидрида 4,15%
Жир	1,2-2,8 % в зависимости от породы. Жировые шарики очень мелкие, молоко не отстаивается, не дает сливок и не сбивается.	2,8-4% жир отстаивается, получаются сливки, сбивается масло.

Константы молочного жира:

Продолжение таблицы

число омыления	210-230	222-232
иодное число	90-100	25-40
температура плавлен. °С	20-24	26-34
Лактоза (молочный жир)	6,7%	4,7%
Витамины С(мг/л)	98-135	9-18
А	300	130-160
Е	650	600-1230
и др.		

The Delphion Integrated View: INPADOC Record

Title: **RU2138955C1: METHOD FOR PRODUCTION OF DRY MILK PRODUCT**

Derwent Title: Method for production of dry milk product [Derwent Record]

Country: **RU** Russian Federation

Kind: **C1** Patent i

High Resolution

Inventor: **MASLOBOEV JU.A.**;
AKHUNOV F.G.;
SULEJMANOV N.T.;
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Assignee: **BASHKIRSKIJ INSTITUT PATENTOVEDENIJA I SERTIFIKATS**
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Published / Filed: **1999-10-10** / 1996-06-07

Application Number: **RU1996000111202**

IPC Code: Advanced: **A23C 9/16**;
Core: **A23C 9/00**;
IPC-7: **A23C 9/16**;

ECLA Code: None

Priority Number: 1996-06-07 **RU1996000111202**

Abstract: FIELD: food production industry. SUBSTANCE: method is used in dairy products industry. According to method, antioxidant agidol in oil solution is introduced in amount of 0.005-0.01 mas.% into raw milk. Mixture is homogenized, thickened and dried. Antioxidant agidol can be introduced into dry milk in dry form by spraying powder in amount of 0.05-0.1 mas.%. Application of aforesaid method allows for reducing and suppressing Cancerogenic symptoms, prolonging period of storing ready product because fat of mare's milk is not made rancid. Vitamins are preserved by 70-80% after one year of storage in non-hermetic vessel. EFFECT:

higher efficiency. 5 cl, 1 tbl, 2 ex

Family:

Buy PDF	Publication	Pub. Date	Filed	Title
☑	RU2138955C1	1999-10-10	1996-06-07	METHOD FOR PRODUCTION OF DRY MILK PRODUCT
1 family members shown above				

Other Abstract Info: None

В3

СОЮЗ СОВЕТСКИХ СОЦИАЛИСТИЧЕСКИХ РЕСПУБЛИК

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ГОСУДАРСТВЕННЫЙ КОМИТЕТ ПО ИЗОБРЕТЕНИЯМ И ОТКРЫТИЯМ ПРИ ГКНТ СССР

ОПИСАНИЕ ИЗОБРЕТЕНИЯ

К АВТОРСКОМУ СВИДЕТЕЛЬСТВУ

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2

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(54) СПОСОБ ЛЕЧЕНИЯ АЛЛЕРГОДЕРМАТОЗОВ У ДЕТЕЙ

(57) Изобретение относится к медицине, в частности к педиатрии, аллергологии и диетотерапии. Цель – сокращение сроков лечения и удлинение ремиссии заболевания. Для этого на фоне гипоаллергенной диеты вводят кумыс по 25 мл/кг массы тела 2 раза в день. 1 табл.

Изобретение относится к медицине, в частности к педиатрии, аллергологии и диетотерапии.

Цель изобретения – сокращение сроков лечения и удлинение ремиссии заболевания.

Поставленная цель достигается тем, что согласно способу диетотерапии аллергодерматозов детям на фоне гипоаллергенной диеты назначают кумыс 2 раза в день в качестве второго завтрака и полдника из расчета 25,0 мл на 1 кг массы тела в сутки. Из рациона исключают другие молочные продукты. Наряду с диетотерапией проводят общепринятое симптоматическое и местное лечение заболевания.

Пример 1. Больной Г., 10 лет, диагноз: нейродермит. Ограниченная форма. Среднетяжелое течение. Дисбактериоз колипротейный II стадии.

С 2-месячного возраста у ребенка отмечались проявления экссудативно-катарального диатеза, связанные с переводом на искусственное вскармливание. Впоследствии развилась детская экзема, которая трансформировалась в нейродермит. Особенностью семейного анамнеза является аллергическая отягощенность: по линии матери у бабушки – ожирение, бронхиальная астма, у матери – поллиноз. У ребенка наблюдались реакции повышенной чувствительности к ряду пищевых продуктов (цитрусовые, шоколад, морковь, томаты). Наблюдался аллергологом, неоднократно лечился в стационаре. При осмотре на коже в области сгибов верхних и нижних конечностей отмечаются воспалительные изменения в виде бляшек, покрытых корочками, на инфильтрированной основе. Беспокоит зуд. В гемограмме – эозинофилия до 10%. По данным ПРИСТ уровень общего IgE 600 Ки/мл, выявлена сенсибилизация к белку куриного яйца. По методу дегрануляции тучных клеток отмечалась сенсибилизация к белкам коровьего молока и куриного яйца. Проведен курс дието-

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терапии предлагаемым способом. В результате лечения наблюдалось быстрое и отчетливое улучшение общего состояния, регрессирование кожных воспалительных явлений с 5-го дня лечения, их полное исчезновение на 25-й день от начала курса лечения. В гемограмме уменьшилось количество эозинофилов. В анализе кала наблюдалось улучшение картины микробиоценоза кишечника. Отмечалась положительная динамика по данным ПРИСТ и РАСТ и дегрануляции тучных клеток. Ребенок за период лечения прибавил в массе 400,0 г, выписан с полной ремиссией.

Пример 2. Больной А., 6 лет, диагноз: нейродермит. Распространенная форма. Тяжелое течение. Период обострения. Дисбактериоз грибковый II стадии.

С 2-летнего возраста страдает детской экземой, которая трансформировалась в нейродермит. Семейный анамнез отягощен по аллергологическим заболеваниям: по линии матери медикаментозная аллергия у дяди.

При осмотре кожный процесс носит распространенный характер, изменения на коже и в виде сгруппированных папулобляшек, локализующихся в области шеи, груди, сгибов верхних и нижних конечностей, на инфильтрированном фоне. Очаги лихенификации, шелушения, трещины, расчесы. В гемограмме эозинофилия до 8%. При обследовании фекалий на дисбактериоз выявлен колигрибковый дисбактериоз II стадии за счет наличия грибов рода Мисоч, отсутствия лактобацилл с титре 10^{-3} мл. По данным ПРИСТ общий IgE 1000 Ки/мл, по данным РАСТ выявлена сенсибилизация к белку коровьего молока, по дегрануляции тучных клеток – к белкам коровьего молока и куриного яйца. Проведен курс диетотерапии предлагаемым способом. В результате лечения отмечено быстрое регрессирование кожных изменений в очагах поражения с полной ликвидацией воспалительных явлений, улучшение общего состояния. В гемограмме отмечалось уменьшение количества эозинофилов. В анализе кала уменьшение интенсивности дисбактериоза кишечника, перешедшего из II стадии в I за счет появления лактобацилл в титре 10^{-1}, исчезновения грибов рода Мисоч. В результате проведенного курса диетотерапии по предлагаемому способу наблюдалась отчетливая динамика показателей, характеризующих уровень сенсибилизации по методу дегрануляции тучных клеток и ПРИСТ. Ребенок в состоянии полного клинического выздоровления на 26-й день выписан домой.

Способ испытан в отделении нарушения питания Казахского НИИ педиатрии на 40 больных детях с аллергодерматозами.

Способ осуществляют следующим образом.

В качестве диетического продукта используют кумыс, который назначают 2 раза в день во время второго завтрака и полдника из расчета 25,0 мл на 1 кг массы тела в сутки. Диетотерапию проводят на фоне гипоаллергенной диеты с исключением молочных продуктов из рациона. Весь курс лечения составляет 20–25 дн. Наряду с диетотерапией проводят общепринятое симптоматическое и местное лечение.

В результате лечения наблюдается быстрое и отчетливое улучшение общего состояния и самочувствия, регрессирование кожных воспалительных явлений на 5–7-й день пребывания в стационаре, их полное исчезновение на 24-й день. В гемограмме уменьшается количество эозинофилов, в анализе кала наблюдается улучшение картины микробиоценоза кишечника, нарастает масса тела. Больные пребывают в стационаре в среднем 24 дн. Положительная динамика также наблюдается по данным ПРИСТ и РАСТ, дегрануляции тучных клеток, что свидетельствует о снижении сенсибилизации.

Реализация действия диетотерапии наблюдается в заметно более ранние сроки, чем диетотерапия с применением кисломолочного продукта "Балдырган", удлиняется ремиссия (см.таблицу).

В рамках предлагаемого способа кумыс оказывает комплексное воздействие на организм больного:

элиминация причинно значимых антигенов, так как наиболее часто встречается сенсибилизация к белкам коровьего молока;

нормализующее воздействие на микробиоценоз кишечника, за счет антибиотических свойств, так как у подавляющего большинства больных отмечается дисбактериоз кишечника и нарушается синтез витаминов микрофлорой кишечника;

за счет того, что кумыс имеет полноценный аминокислотный состав, а белки кумыса представлены, в основном, легкоусвояемой ульбуминовой фракцией, кумыс эффективно восполняет потерю белка, которая происходит в связи с кожным и воспалительным процессом (мокнутием и шелушением);

за счет седативного действия кумыса у больных улучшается сон, уменьшается кож-

ный зуд, снимается повышенная нервная возбудимость.

Таким образом, предлагаемый способ диетотерапии более эффективен по сравнению с известным, что обусловлено патогенетической адекватностью диеты для детей, страдающих кожными формами аллергических заболеваний.

Формула изобретения

Способ диетотерапии аллергодерматозов у детей, включающий введение кисломолочных продуктов, отличающийся тем, что, с целью сокращения сроков лечения и удлинения ремиссии заболевания, используют кумыс по 25 мл/кг массы тела 2 раза в день.

Динамика клинических проявлений у больных аллергодерматозом на фоне различных диет

Группы больных	Кол-во больных	Улучшение общего состояния и самочувствия, дн от начала лечения	Регресс воспалительного процесса на коже, дн от начала лечения	Сроки лечения, дн	Длительность ремиссии, мес
Диета с "Балдырганом" (известный способ)	98	11±0,3	32,1±2,17	40±1,0	20±2,1
Диета с кумысом (предлагаемый способ)	40	6±0,19 $p \leq 0,01$	26±1,31 $p \leq 0,01$	27±1,9 $p \leq 0,01$	28±2,3 $p \leq 0,01$

Составитель Л.Столярова
Редактор А.Огар Техред М.Моргентал Корректор О.Кундрик

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EXHIBIT 3

0790145

SPECIFICATION OF AUTHOR'S CERTIFICATE

(19) SU (11) 1740002 A1
(51) 5 A 61 K 35/20

(21) No 4695512/14

(22) 26.05.89

(46) 15.06.92 Bul. No22

(71) The Institute of Regional Problems of Nutrition of the Academy of Medical Sciences of the USSR and the Research Institute of Pediatrics of the Ministry of Public Health of the Republic of Kazakhstan

(72) T.Sh. Sharmanov, M.A.Akhmetova, R.G.Eginchibaeva, S.A. Nikitin, S.E. Akhmetova and A.K. Mashkeev

(53) 616. 085 (088.8)

(56) Akhmetova M.A. et al.. The problems of nutrition of a healthy and sick child. Alma-Aty, 1980, p.76

(54) METHOD OF TREATMENT OF ALLERGODERMATOSES IN CHILDREN

(57) The invention relates to medicine, specifically pediatrics, allergology and dietary cure. Object – to reduce the time of treatment and elongation of remission of a disease, for which purpose koumiss is administered in the presence of hypoallergen diet, 25 ml/kg of a body weight, twice a day, one tablet.

The invention relates to medicine, particularly pediatrics, allergology, and dietary cure.

An object of invention – reduction of the time of treatment and lengthening of remission of a disease.

Said object is achieved owing to the fact that according to a method of the dietary cure of allergodermatoses, in the presence of a hypoallergen diet, koumiss is administered to children twice a day as a lunch and in the afternoon, 25.0 ml per kg of a body weight daily. A

ration is devoid of other milk products. Conventional symptomatic and local treatment of diseases is carried out along with said dietary cure.

Example 1. Patient G., aged 10; diagnosis: neurodermit. Limited form. Average severity course. Coli-disbacteriosis, II Degree.

Since the age of two months, the child has shown symptoms of exudative – catarrhal diathesis associated with a change-over to artificial bringing-up. Child's eczema developed afterwards that transformed into neurodermit. A specific feature of family history is allergization: in the grandmother, mother's line—obesity, bronchal asthma; pollinosis – in the mother. Reactions of enhanced sensitivity were observed in the child to some food products (citrus fruit, chocolate, carrots, tomatoes). Observed by an allergist, underwent treatment in hospital many a time. On examination, inflammatory changes observed in the area of bends of the upper and lower limbs on the skin in the form of incrustated plaques on an infiltrated base. Itching. Hemogram: zozinophilia about 10%. According to PRIST data the total IgE level is 600 Ki/ml; sensitization to a chick egg white revealed. Using a method of degranulation of fatty cells sensitization observed to cow milk chick egg albumins. A course of dietary cure carried out by the method proposed. The result: a rapid, marked improvement of general conditions. Regression of skin inflammatory symptoms since the fifth day of treatment, their complete disappearance on the 25th day of the start of treatment. Hemogram: a reduced amount of zozinophils. Dung assay: the improved picture of a microbiocenosis of the intestines. Positive dynamics according to PRIST and RAST data and fatty cells degranulation. The child gained 400.0 g in weight over a period of treatment. Released with complete remission.

Example 2. Patient A. Aged 6 years. Diagnosis: neurodermit. Common form. Critically ill. Period of exacerbation. Disbacteriosis, fungous, II Degree. Suffers from child's eczeme since the age of two years that transformed into neurodermit. Family history burdened by allergologic diseases: mother's line—medicamental allergy in the uncle.

On inspection, a cutancous process is of a common nature, alterations on the skin and in the form of grouped papule plaques localized in the area of the neck, the chest, bends of the upper and lower limbs against an infiltrated background. Zones of lichenification, desquamation, cracks, combing. Hemogram: zozinophilia about 8%. On examination of excrements for disbacteriosis, fungous coli-bacteriosis, II Degree, detected due to the presence of fungi of the genus Misoch, absence of lactobacilli in a 10^{-3} titer. According to PRIST, the total IgE is 1000 Ki/ml. According to RAST, sensitization was revealed to a cow milk albumin, according to degranulation of fat cells – to cow milk/chicken egg albumins. A course of dietary cure was carried out according to the claimed method. The result: rapid regression of skin alterations in killing zones with the complete remedy of inflammatory symptoms, improvement of general conditions. Hemogram: a reduced amount of zozinophils. Examination of excrements: the reduced intensity of a disbacteriosis of the intestines transformed from II Degree into I Degree because of the appearance of lactobacilli in a 10^{-1} titer, disappearance of fungi of the genus Misoch. As a result of a course of dietary cure under the method proposed a clear-cut dynamics of indices was observed to characterize the level of sensitization according to the method of degranulation of fatty cells and the PRIST. The child released on the 26th day in a state of complete clinic convalescence.

The method was tested in the Kazakh Research Institute of Pediatrics on 40 children having allergodermatoses.

The method is carried out in the following fashion.

The dietetic product used is represented by koumiss administered twice a day during a lunch and in the afternoon, 25.0 ml per kg of a body weight daily. Dietary cure is carried out in the presence of a hypoallergen diet, with milk products eliminated from the ration. The entire course of treatment 20-25 days. Said dietary cure is carried out concurrently with common symptomatic and local treatment. The result: improvement of general conditions and state of health, regression of skin inflammatory symptoms on the 5th – 7th day of

hospitalization, their complete disappearance on the 24th day. Hemogram: a reduced amount of zozinophils. Dung assay: an improved picture of microbiocenosis of the interstines, an increased body weight. Patients stay in hospital on the average 24 days. Positive dynamics is likewise observed according to PRIST and RAST data, degranulation of fatty cells, which fact affirms sensitization.

Realization of dietary cure effects is observed in periods markedly earlier than said dietary cure using a lactic acid product "Baldyrgan". Remission extends. (Cf. Table).

In the format of the method as proposed, koumiss produces comprehensive effects on a patient's organism:

elimination of cause-significant antigens because sensitization to cow milk albumins occurs most frequently;

normalizing effects on a microbiocenosis of the intestines due to the antibiotic properties, because in the overwhelming majority of patients there is observed a disbacteriosis of the intestines and the synthesis of vitamins is disturbed by the intestinal microflora;

owing to the fact that koumiss has a full value amino acid formulation and said koumiss albumins are represented by generally a readily available albumin fraction said koumiss makes good an albumin loss quite well that occurs in connection with a cutaneous and inflammatory process (festering, desqumation);

on account of the sedative effect of koumiss, patients' sleep becomes more sound, skin intense itching abates, and high nerve excitability is relieved.

Thus, the method of dietary cure as proposed is more effective than the conventional, which fact is attributable to pathogenetic adequacy of a diet for children who suffer from the cutaneous forms of allergic diseases.

CLAIMS

A method of dietary cure of allergodermatoses in children comprising administering lactic acid products, characterized in that the reduce the time of treatment and lengthen the remission of a disease, use is made of koumiss on the basis of 25 ml/kg of a body weight twice a day.

Dynamics of clinical manifestations
in patients suffering from allergodermatosis
in the presence of various diets

Group	Number	Improvement of general condition and state of health, days, from start of treatment	Regression of inflammatory process on skin, days from start of treatment	Time of treatment days	Duration of remission, months
"Baldyrgan" diet (known method)	98	11±0.3	32.1±2.17	40±1.0	20±2.1
Koumiss diet (proposed method)	40	6±0.19 p≤0.01	26±1.31 p≤0.01	27±1.9 p≤0.01	28±2.3 p≤0.01

пер. Цыганков В.В.

261-60-52

EXHIBIT 4

PATENT
Customer No.: 32425

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bodo KUKLINSKI *et al.*	Confirmation No. 6370
Serial No.: 10/511,882	Group Art Unit: 1657
Filed: October 19, 2004	Examiner: Schuberg, Laura J.
For: USE OF A MARE'S MILK CONCENTRATE DRIED ON A HIGHLY-DISPERSED, BIOLOGICALLY INERT MATRIX	Atty. Dkt. No.: SONN:057US

DECLARATION OF DR. NORBERT FUCHS

I, Norbert Fuchs, declare as follows:

1. I am an Austrian citizen, and my place of residence is Bruckdorf 135, Mariapfarr, Austria, A-5571.

2. I am an inventor of the above-referenced patent application. I am employed by Nutropia Ernährungsmedizinische Forschungs GmbH, which is the assignee of the above-reference patent application.

3. I am providing this declaration to present additional data showing that orally administering a mare's milk concentrate dried on a biologically inert, disperse matrix is therapeutically effective in treating human patients with neurodermatitis or psoriasis. The data are attached as Appendix 1.

4. The dried mare's milk concentrate used in the studies described below was formulated as described on page 19, line 7 to page 20, line 1 of the patent application. Following a baseline

examination, 1, 2, or 3 tablespoons (depending on the patient's age; *see* page 20 of the patent application for dosage details) of the dried mare's milk concentrate was administered to the patients once per day. Follow-up examinations were performed approximately one month, two months, and three months after the baseline examination. Patients were permitted to use greasing ointments and oil baths during the course of the study, but no other treatments of their neurodermatitis or psoriasis were permitted.

5. For the treatment of neurodermatitis (ND), the SCORAD (Severity Scoring of Atopic Dermatitis) index was used to qualitatively and quantitatively assess the degree of severity of the atopic eczema. As described on pages 22-23 of the patent application, SCORAD allows the standardized judgment of the degree of intensity of six typical morphologic changes (intensity), the portion of the affected skin area (%), and the subjective assessment of itching and sleep loss using a visual analog scale. The SCORAD index calculation uses the following formula $A/5 + 7B/2 + C$, where A = degree of expansion, B = intensity, and C = subjective symptoms. The SCORAD index has a range from 0-103. A SCORAD < 15 indicates mild ND, a SCORAD $> 15 < 40$ indicates moderate ND, and a SCORAD > 40 indicates severe ND.

6. Nine patients with moderate to severe ND were treated with the dried mare's milk composition as described in paragraph 4 above. As shown in the table and graph on page 4 of Appendix 1 the mean SCORAD decreased from a baseline of 34 to 22 at the first follow-up examination, 14 at the second follow-up examination, and 10.3 at the third follow-up examination. Improvement in SCORAD was evident in many of the patients by their first follow-up visit. By the third follow-up visit, eight of the nine patients had only mild ND

(SCORAD < 15). The only patient not to achieve a SCORAD < 15 still showed dramatic improvement from a SCORAD = 49 to a SCORAD = 17.

7. Photographs of two of the patients in the ND study described in paragraph 6 are provided on pages 5-13 in Appendix 1. Baseline photographs of patient MU were taken on May 27, 2002. Patient MU was photographed approximately two months later on July 22, 2002. Visual improvement in MU's ND is evident between the two sets of photographs. Baseline photographs of patient PC were taken on May 16, 2002. Patient PC was photographed approximately two months later on July 11, 2002. Visual improvement in PC's ND is evident between the two sets of photographs.

8. For the treatment of psoriasis, the Psoriasis Area and Severity Index (PASI) was used. This index takes into account the surface area of the affected skin as well as the extent of inflammation and excessive cell division. To this end, the investigator determines redness, thickening, and scaling for one focus each on the head, trunk, arms and legs, using a scale from 0 to 4. The counts are multiplied by an estimate of the total body area involved. From this calculation results a PASI of between 0 and 96.

9. Twelve patients with psoriasis were treated with the dried mare's milk composition as described in paragraph 4 above. The patients had baseline PASI scores of between 0.5 to 55.2. As shown in the table and graph on page 15 of Appendix 1, the mean PASI decreased from a baseline of 11.4 to 6.8 at the first follow-up examination, 4.3 at the second follow-up examination, and 3.8 at the third follow-up examination. Improvement was most dramatic in patients with the highest baseline PASI scores. For example, patient 12 improved from a baseline PASI = 55.2 to a PASI = to 3.2 at the third follow-up examination.

10. Photographs of two of the patients in the psoriasis study described in paragraph 9 are provided on pages 16-25 in Appendix 1. Baseline photographs of patient BM were taken on April 22, 2002. Patient BM was photographed again on August 1, 2002. Visual improvement in BM's psoriasis is evident between the two sets of photographs. Baseline photographs of patient HR were taken on April 25, 2002. Patient HR was photographed again on July 25, 2002. Visual improvement in HR's psoriasis is evident between the two sets of photographs.

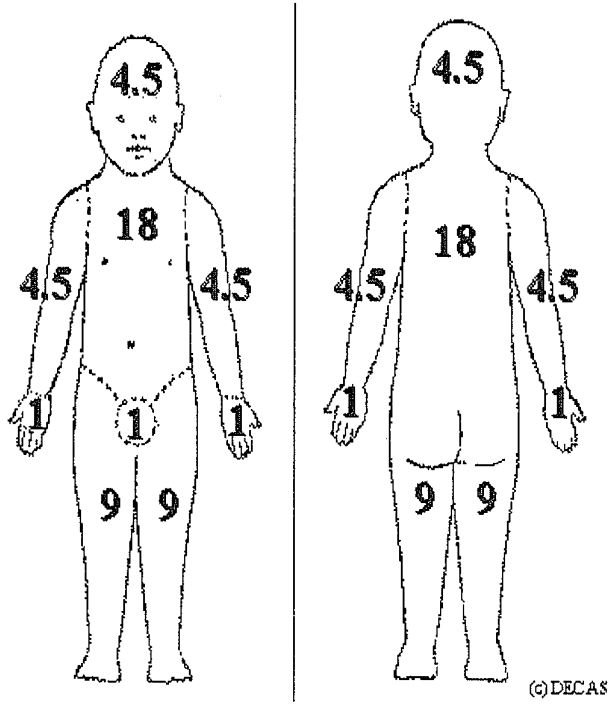
11.I declare that all statements made of my knowledge are true and all statements made on the information are believed to be true; and, further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued thereupon.

Date: July 16 / 2008

Dr. Norbert Fuchs

APPENDIX 1

target parameters
SCORAD



Severity **Sco**ring of **A**topic **D**ermatitis:

Assessed are: the degree of six typical morphological changes (intensity), the portion of the affected Surface of the skin (%), the subjective perception of pruritus, and sleep loss based on a visual analog scale, as well as the total score.

SCORAD – Index calculation

A = degree of expansion

B = intensity

C = subjective symptoms

SCORAD = A/5 + 7xB/2 +C

Intensity is assessed to be most important.

SCORAD - Index

0 – 103 possible

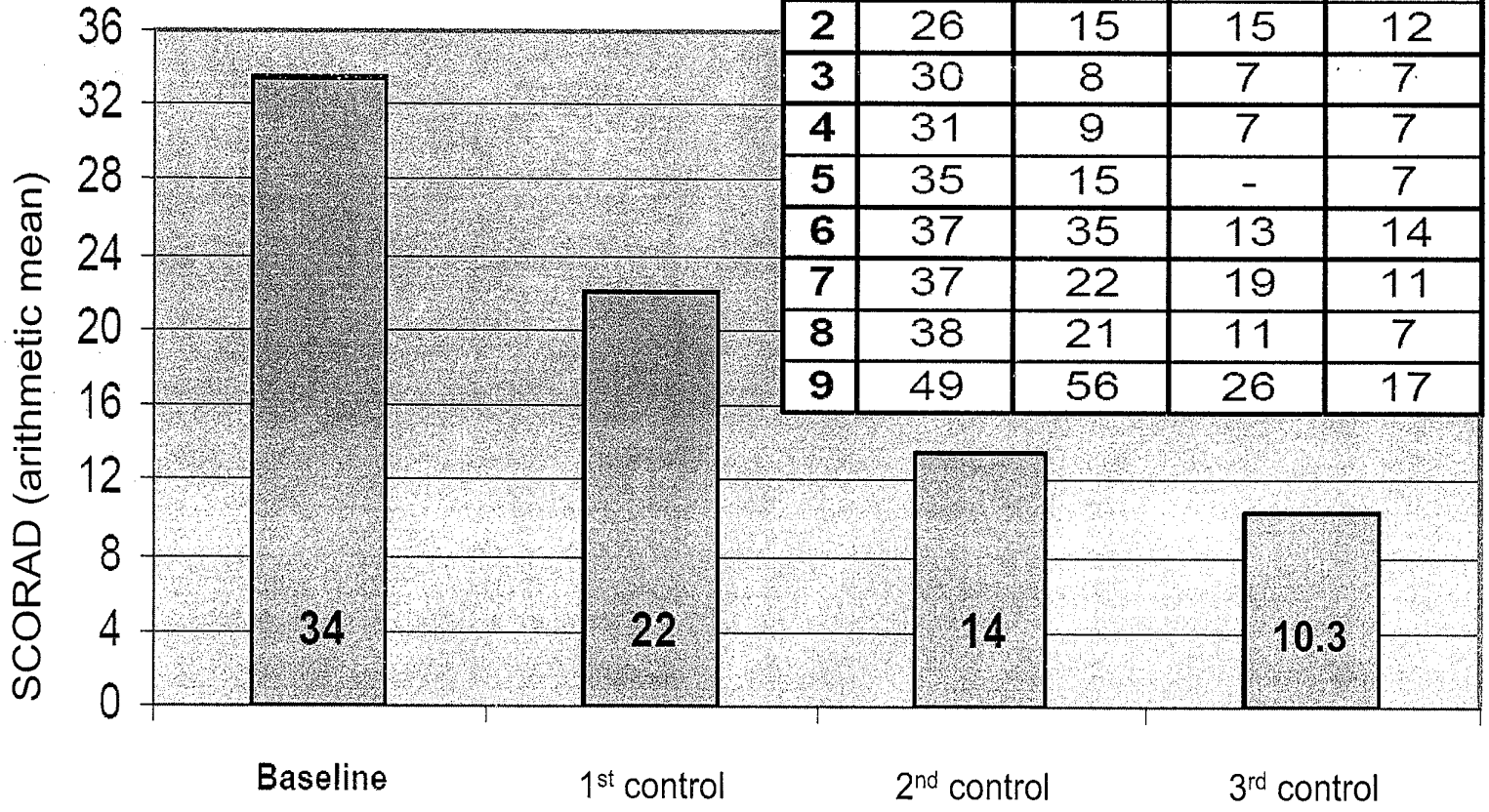
mild ND = SCORAD < 15

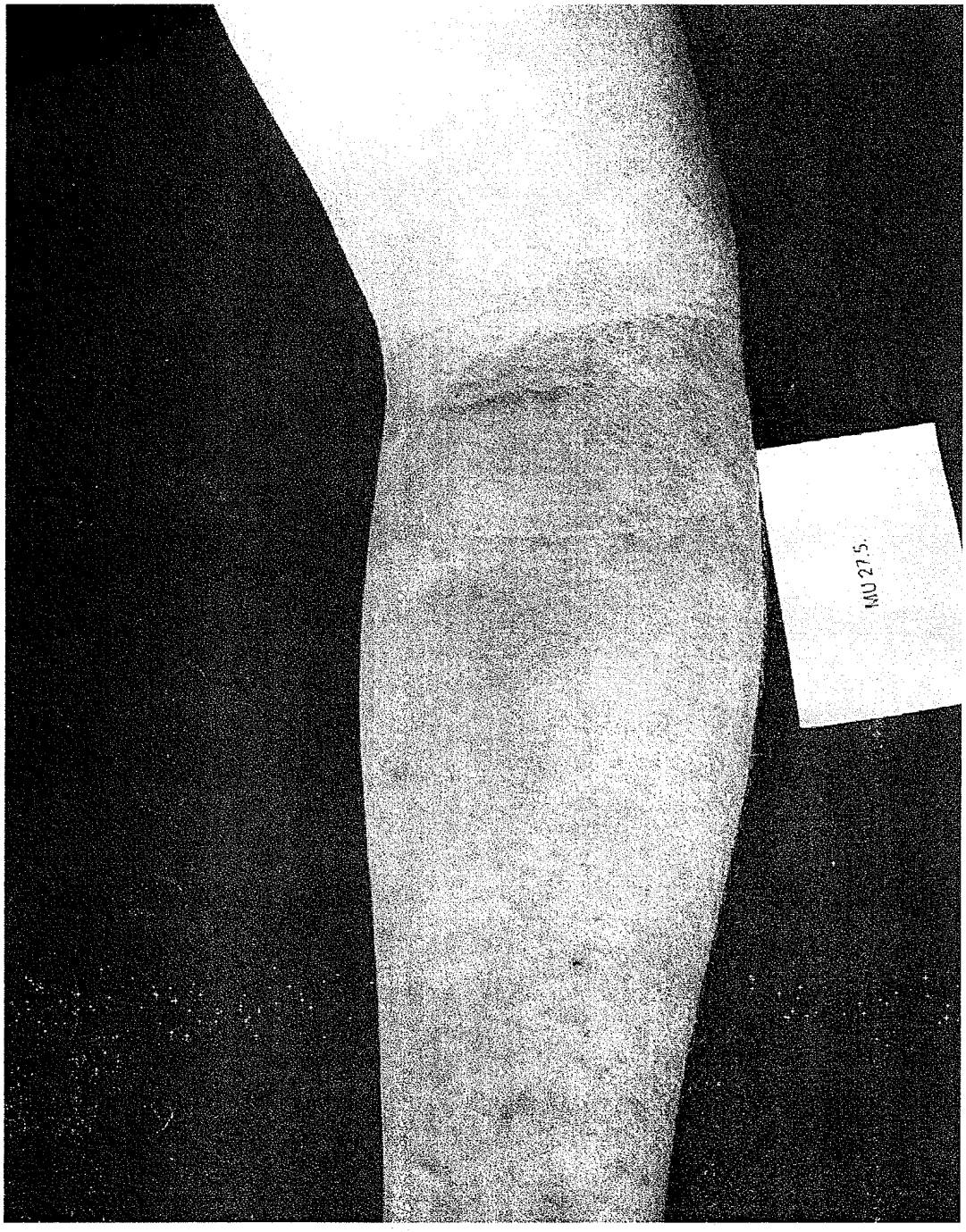
medium/moderate ND = SCORAD > 15 < 40

severe ND = SCORAD > 40

neurodermatitis (n=9)

	Baseline	1st control	2nd control	3rd control
1	19	17	11	11
2	26	15	15	12
3	30	8	7	7
4	31	9	7	7
5	35	15	-	7
6	37	35	13	14
7	37	22	19	11
8	38	21	11	7
9	49	56	26	17

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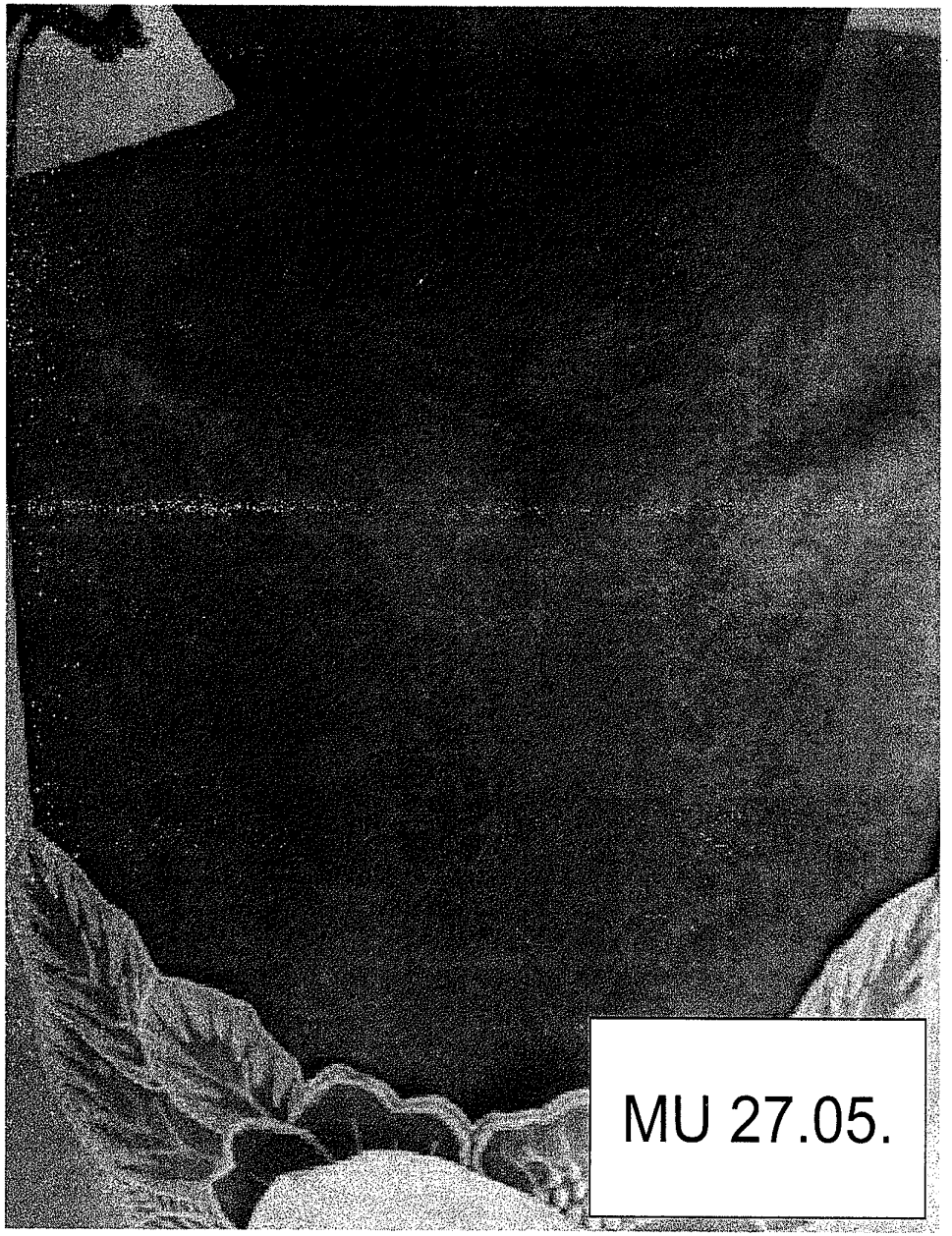
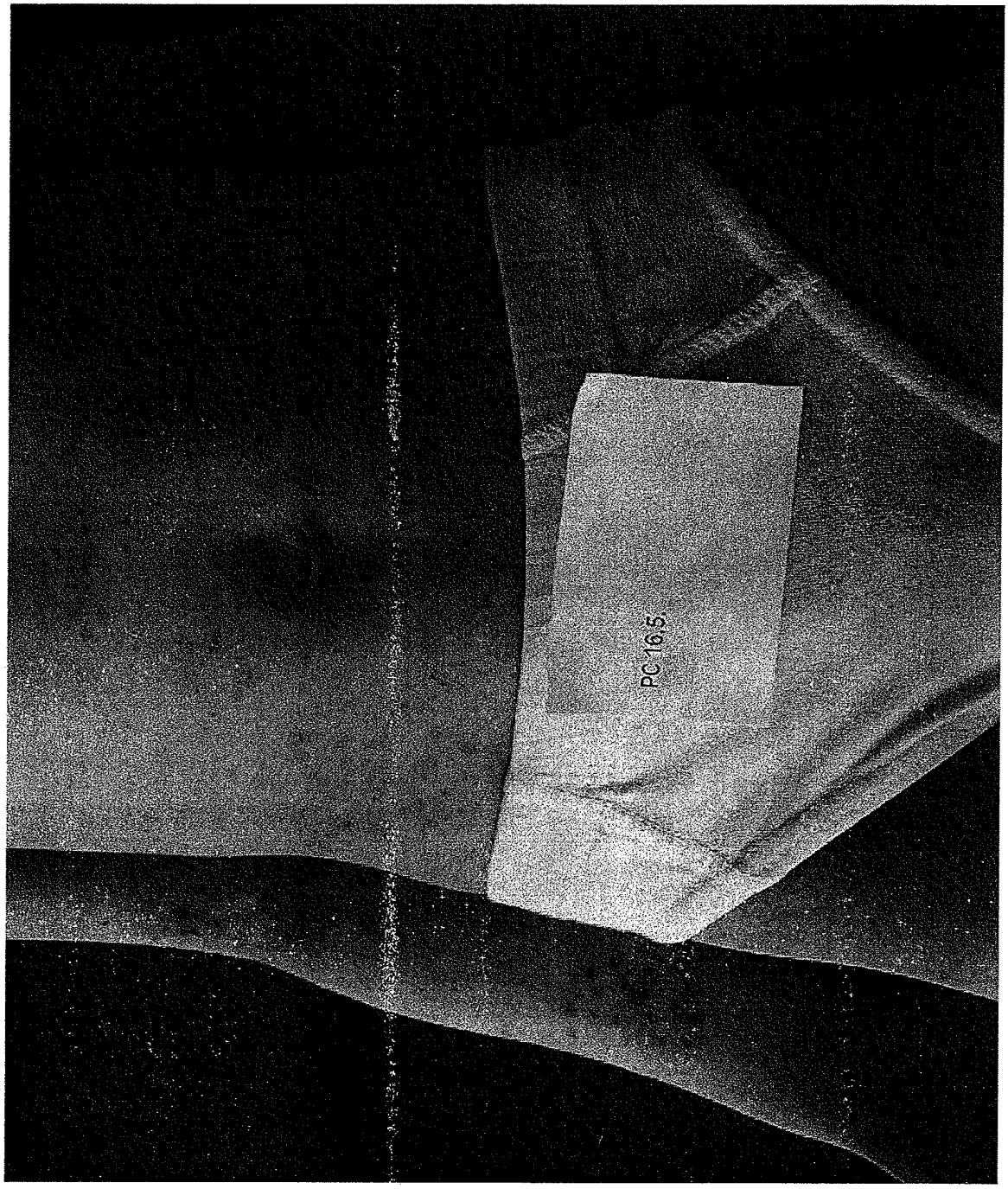
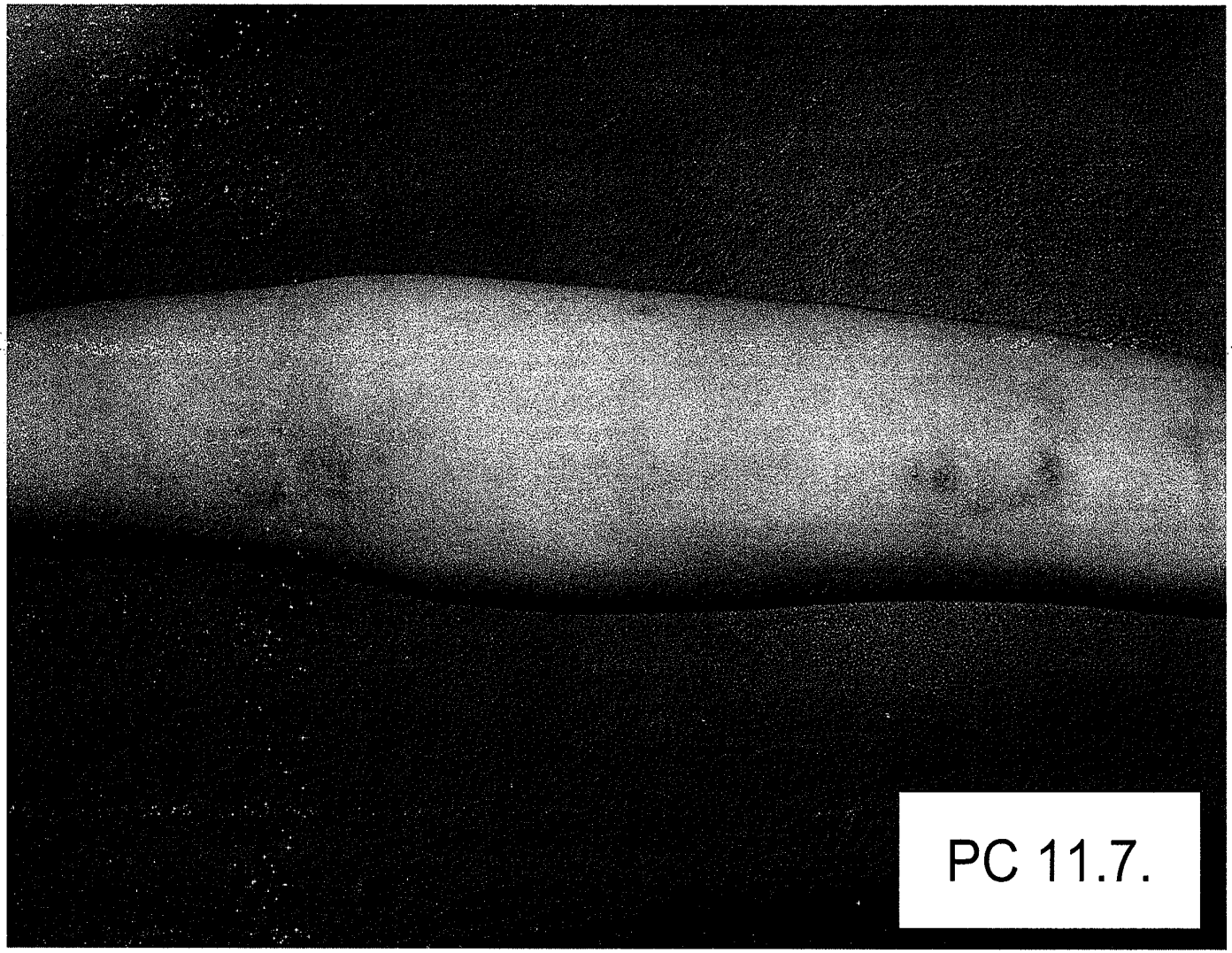

MU 27.05.

MU 22.07.

MU 22. 7.


PC 16.5.

PC 16.5.


PC 11.7.

PC 11.7.

PC 11.7.

psoriasis

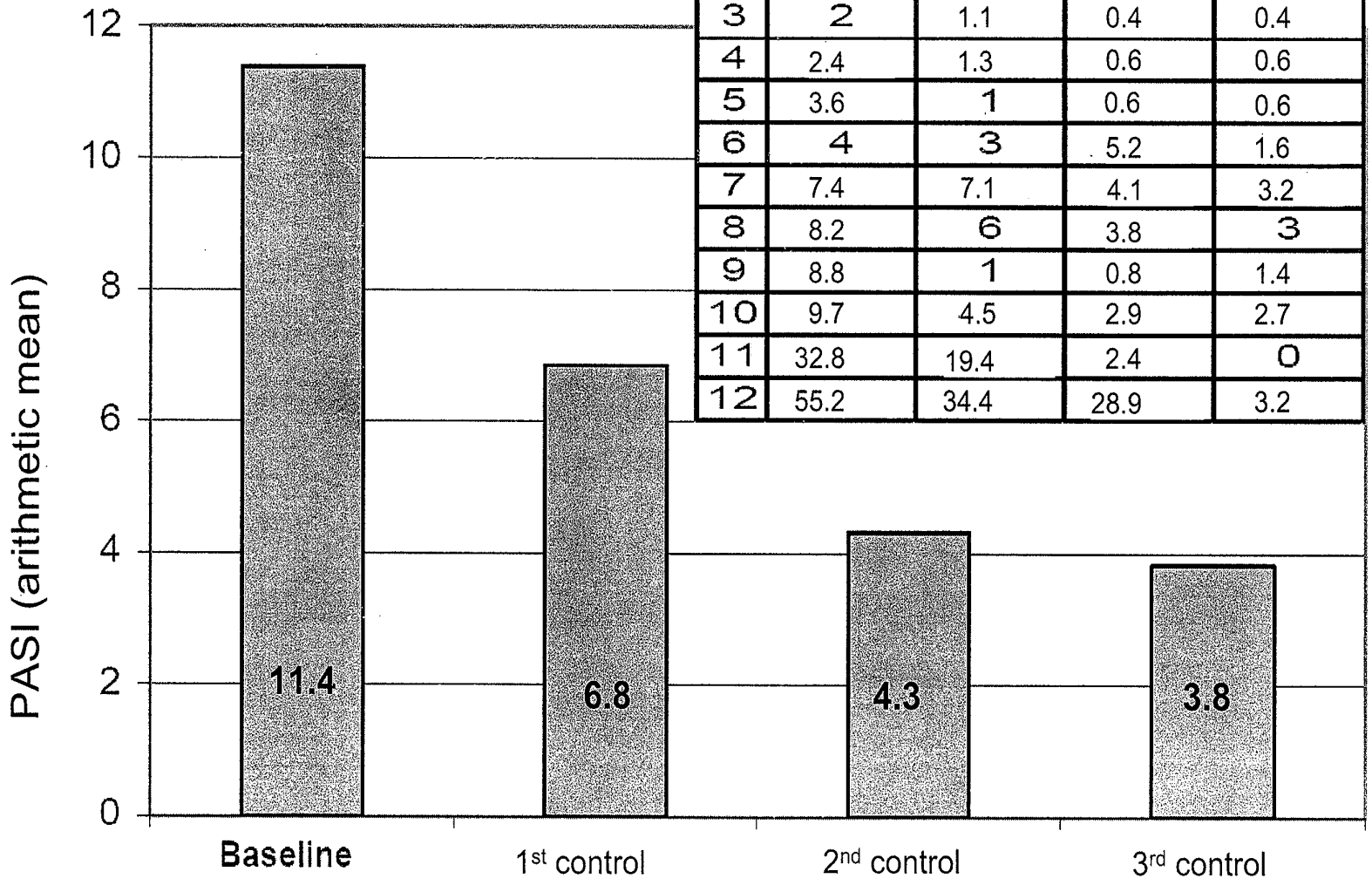
Primary parameter: PASI INDEX

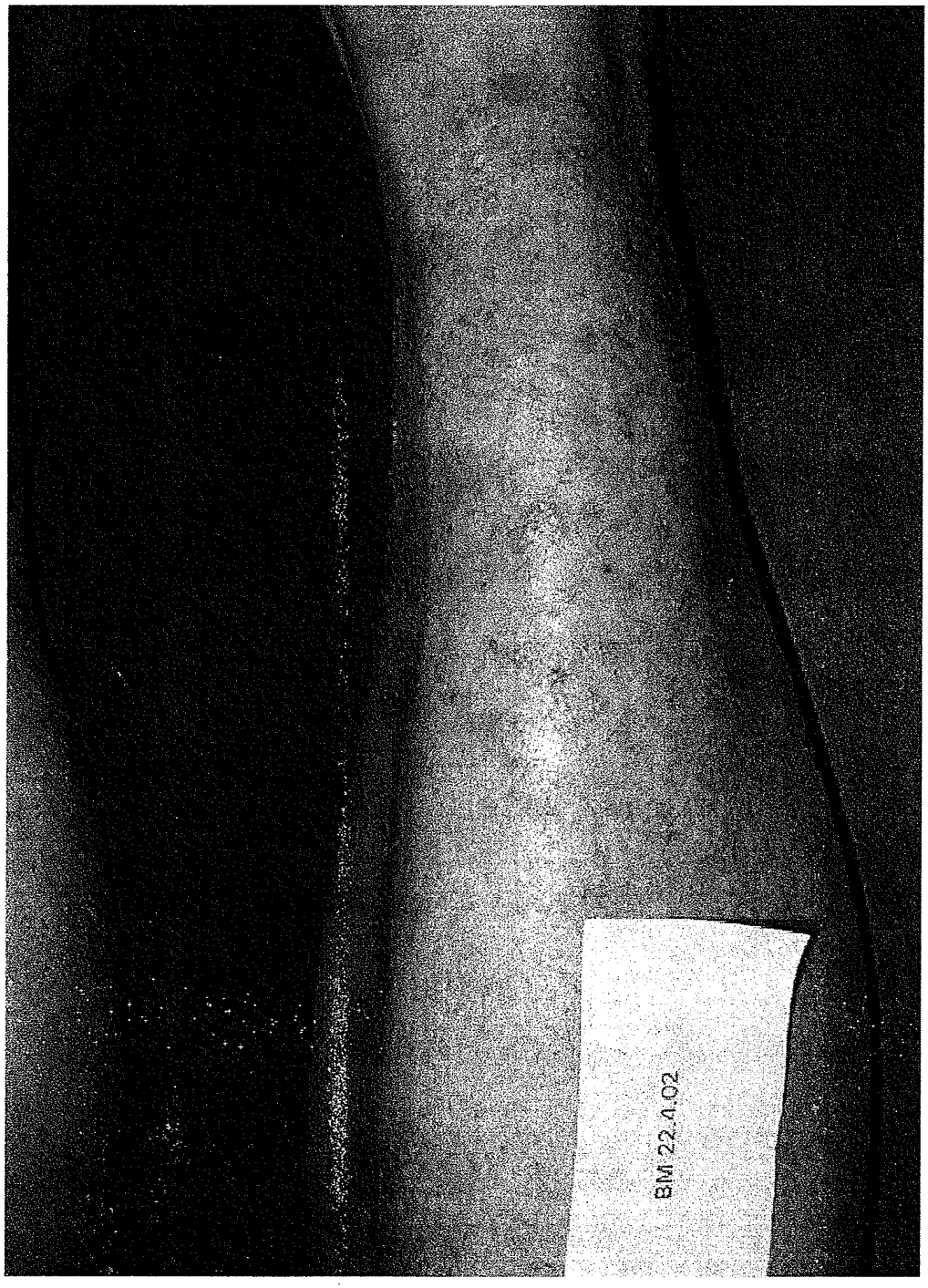
Psoriasis **A**rea and **S**everity **I**ndex

- Degree of expansion and intensity of typical morphological changes of the surface of the skin are assessed. The body is divided up into 4 sections (legs, trunk, arms, head), the point score additionally reflects intensity of the parameters pruritus, reddening (erythema), skin scales and thickness of the skin.

psoriasis (n=12)

	Baseline	1st control	2nd control	3rd control
1	0.5	2.1	1.7	1.9
2	1.8	1.2	0.6	0.4
3	2	1.1	0.4	0.4
4	2.4	1.3	0.6	0.6
5	3.6	1	0.6	0.6
6	4	3	5.2	1.6
7	7.4	7.1	4.1	3.2
8	8.2	6	3.8	3
9	8.8	1	0.8	1.4
10	9.7	4.5	2.9	2.7
11	32.8	19.4	2.4	0
12	55.2	34.4	28.9	3.2

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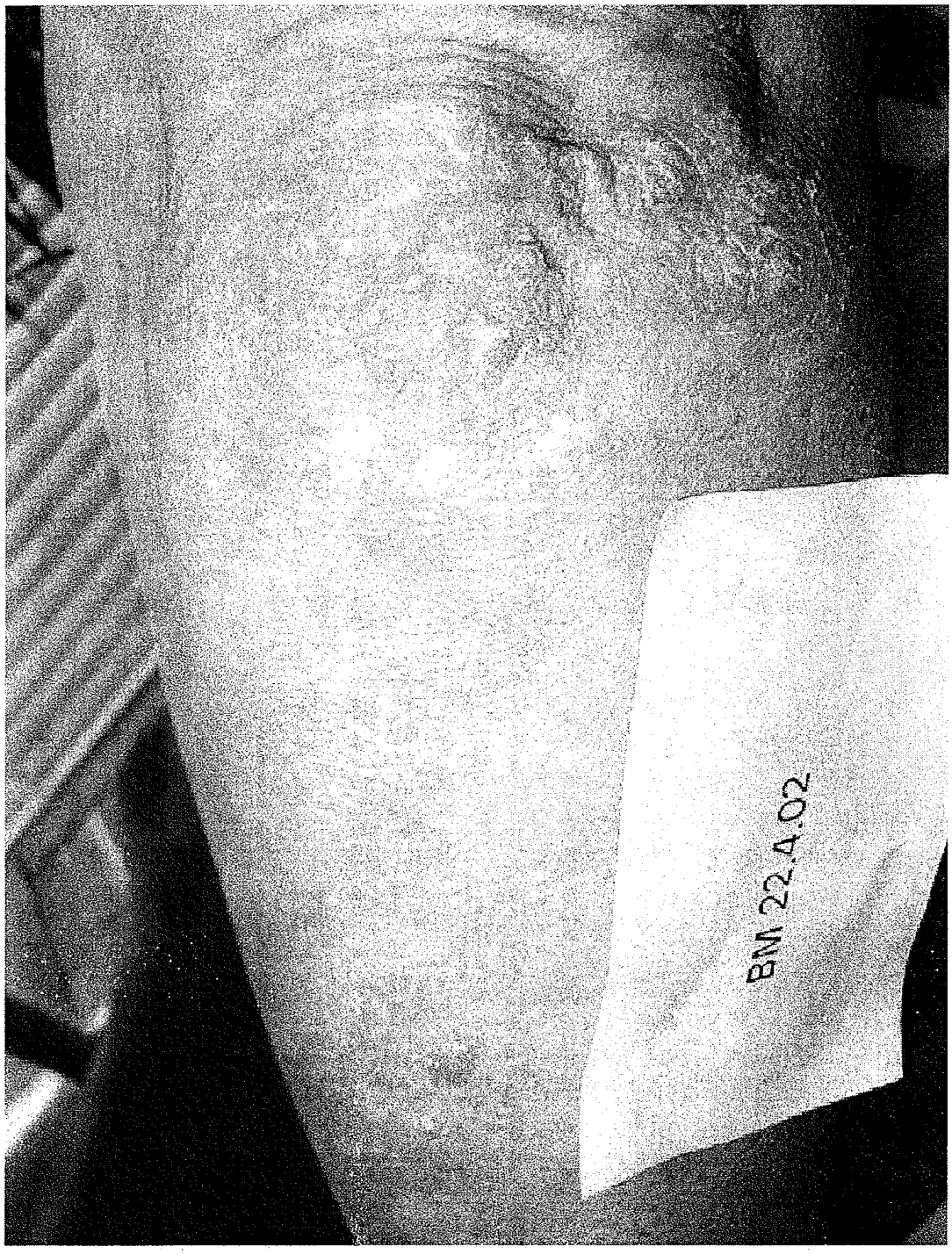
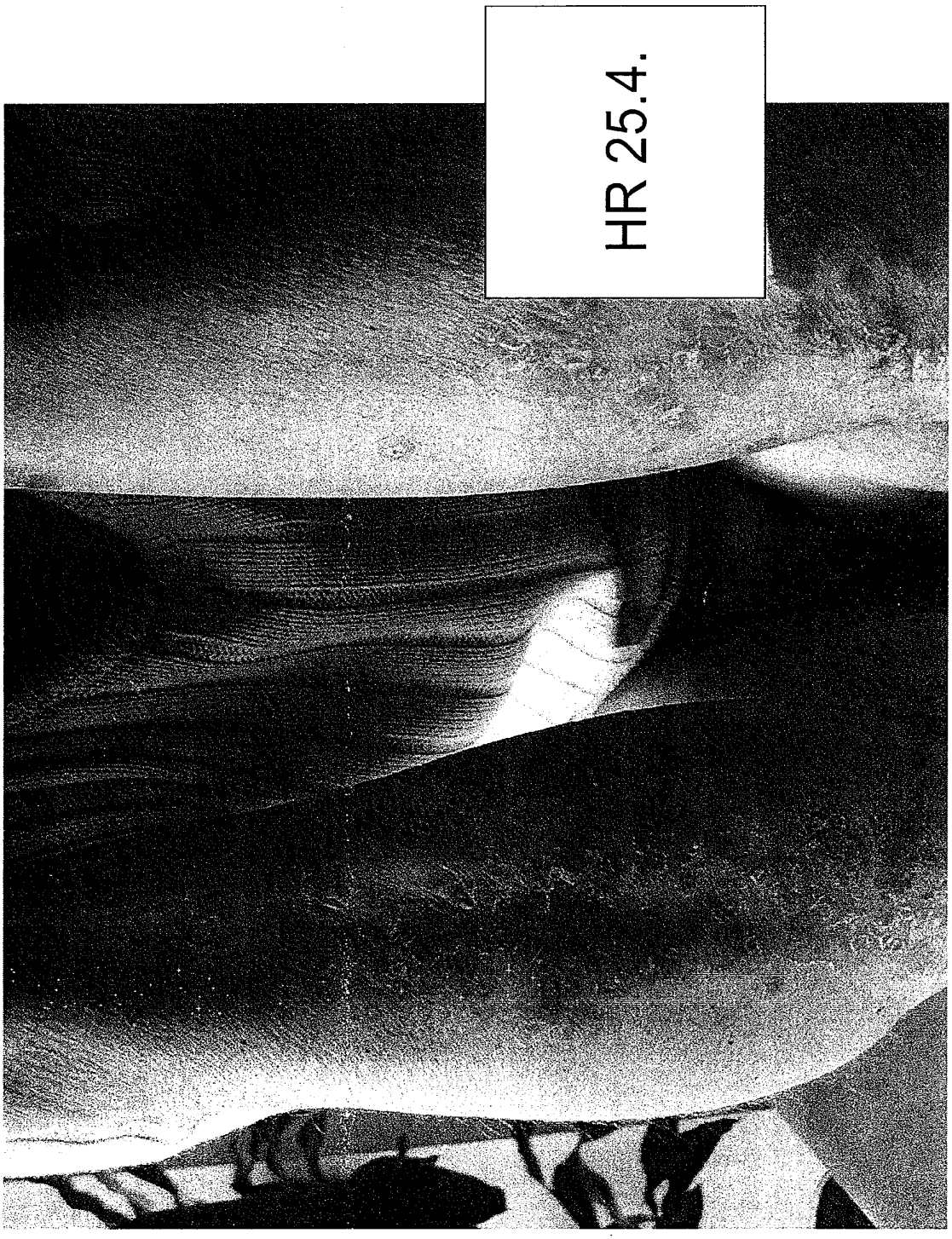

BM 22.4.02

BM1.8.

BM 1.8.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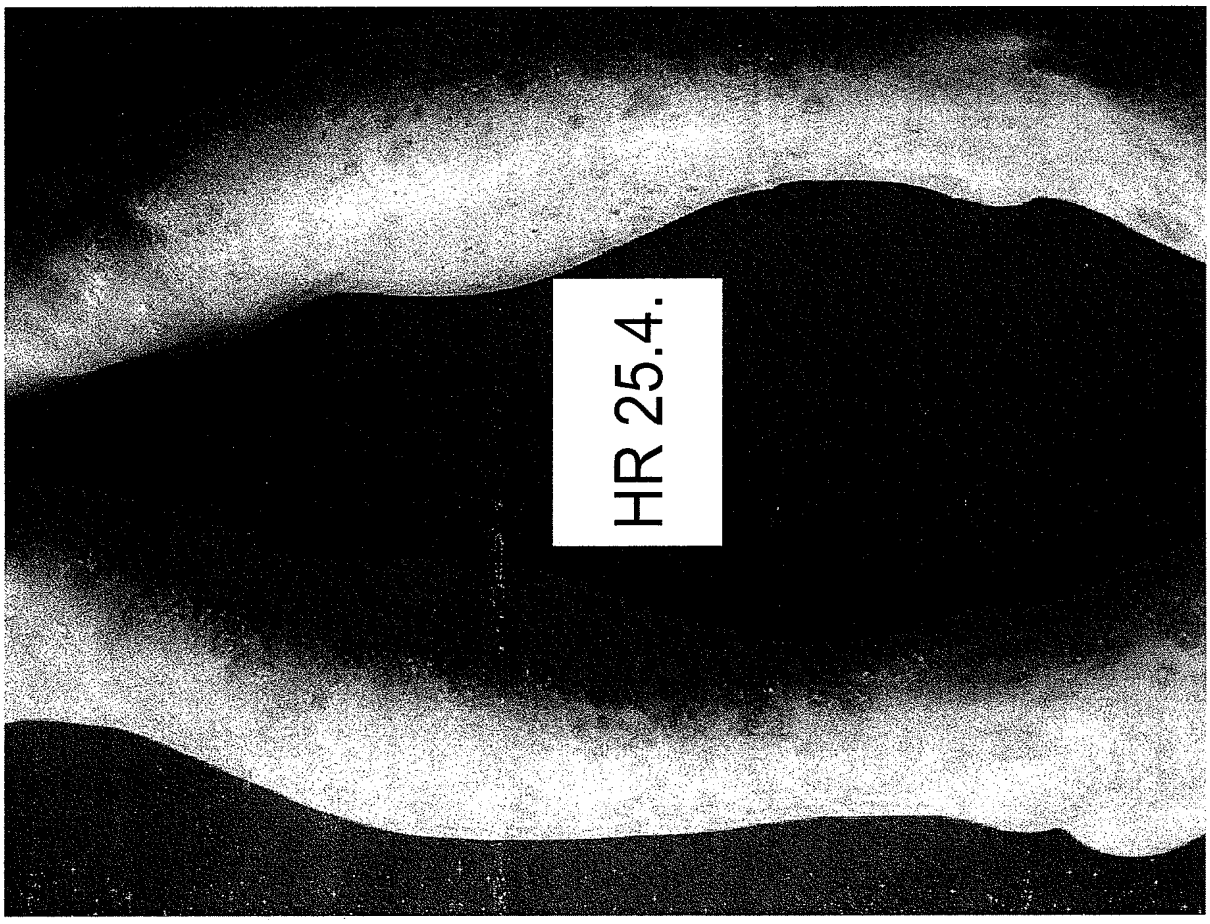
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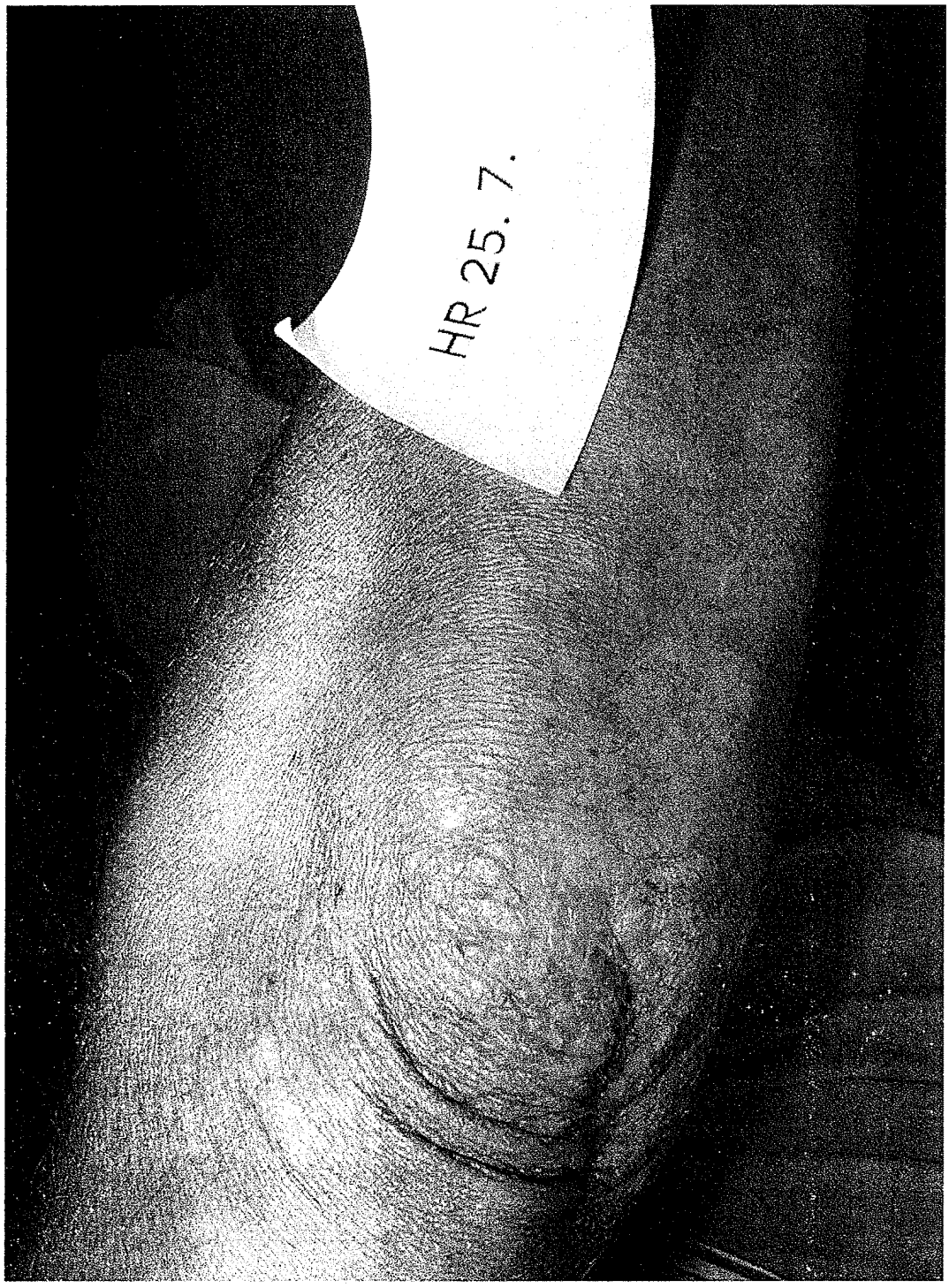
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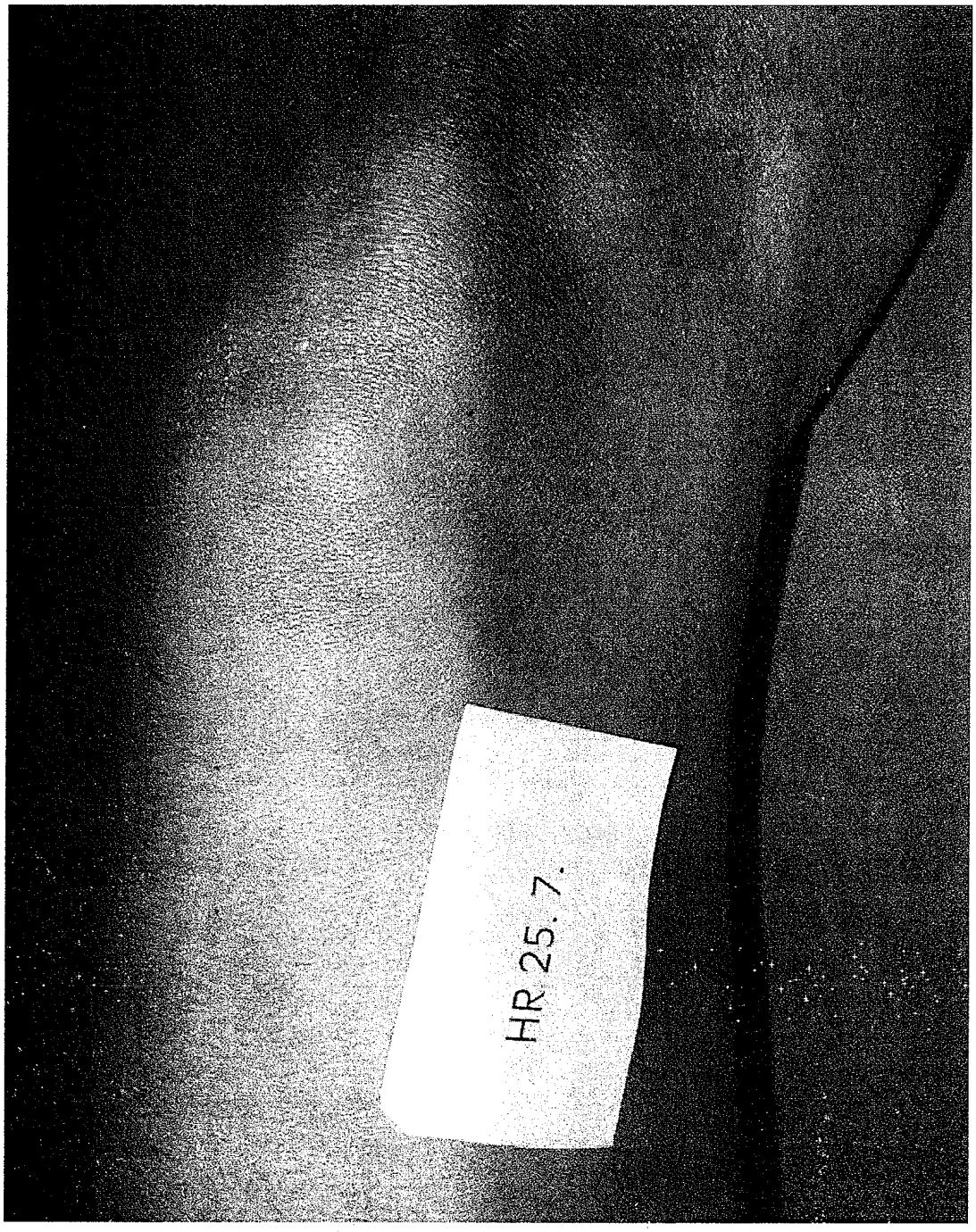
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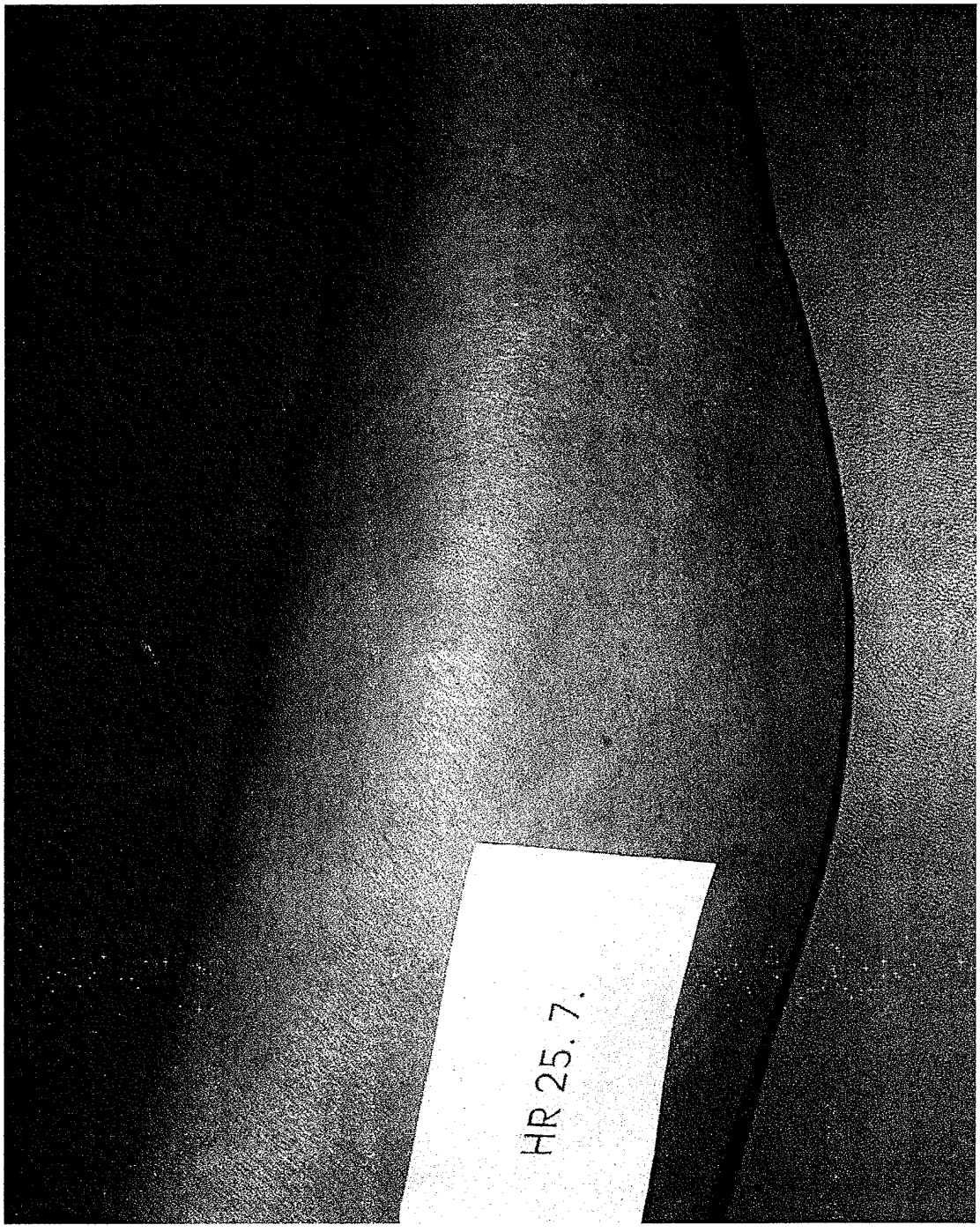
HR 25. 7.

HR 25. 7.